REPORT TO CONGRESS

COST-EFFECTIVENESS DEMONSTRATION OF MEDICARE COVERAGE OF INFLUENZA VACCINE

Louis W. Sullivan
Secretary
Department of Health and Human Services
1990

ACKNOWLEDGEMENT

This report is based on a study conducted by Abt Associates, Inc., for the Health Care Financing Administration (Cost-Effectiveness Study of Medicare Coverage of Influenza Vaccine, Contract No. 500-89-0049)

TABLE OF CONTENTS

CONTENTS (continued)

EXECUTIVE SUMMARY

Legislative Background

The Omnibus Budget Reconciliation Act (OBRA) of 1987 ($4071) mandated a demonstration of the cost-effectiveness of providing influenza vaccine as a covered benefit for Medicare beneficiaries. The demonstration was to be implemented by October 1, 1988. Influenza vaccine will be a covered benefit on November 1, 1990, if the Secretary of the Department of Health and Human Services reports that it has been found to be cost-effective. If data are inadequate for a determination by that date, the demonstration must continue for an additional 2 years. At the end of this period and no later than April 1, 1993, the Secretary must report on the cost-effectiveness of Medicare coverage. Unless the report finds that an influenza benefit would not be cost-effective, coverage will be extended to all eligible beneficiaries within 1 month of the submission of the report.

The legislation requires an annual expenditure of $25 million for the demonstration. In assessing cost-effectiveness, the Secretary is to consider direct vaccine costs, utilization of vaccine that otherwise might not have occurred, and the cost of illness and nursing home days avoided. Additional years of life, and the additional Medicare expenditures incurred during these years, are not to be used to reduce the estimate of cost-effectiveness.

The Health Care Financing Administration (HCFA), working in cooperation with the Centers for Disease Control (CDC), was given responsibility for implementing the demonstration and completing the cost-effectiveness study.

The demonstration will be evaluated to determine whether Medicare coverage of influenza vaccine increases vaccination rates among eligible beneficiaries. To determine the cost-effectiveness of Medicare coverage, the evaluation will assess the potential of any changes in vaccination rates brought about by Medicare coverage to lower hospitalization and mortality rates for influenza-related conditions. The costs to Medicare of vaccine coverage will be compared to the gains to the Medicare program in reduced influenza-related payments, to indicate the net costs or savings of a Medicare influenza vaccine benefit.

Demonstration Design

With the assistance of a consultant and a Technical Assistance Group (TAG), HCFA and CDC developed a design for the demonstration with the following characteristics.

- Each demonstration site includes an intervention area, where Medicare subsidized influenza vaccine is provided to all eligible beneficiaries, and a comparison area, matched in terms of demographic and health services utilization characteristics to the intervention area, in which subsidized vaccine is not provided. This design facilitates a concurrent comparison of vaccination rates and outcomes between areas.

- Sites were defined as counties, groups of counties, and entire States. Within each site, physicians, public health clinics, nursing homes, hospitals, and home health agencies were targeted as vaccine providers.

- Payments of $8.00 per dose for physicians and hospitals, and $4.00 per dose for other providers were authorized for administration of vaccine to Medicare Part B-eligible beneficiaries living in the intervention areas. Vaccine was to be bulk purchased by the Federal Government. No Part B coinsurance or deductible applies. Providers must accept assignment for administering the vaccine.

- Demonstration projects were required to engage in outreach activities to inform beneficiaries and providers of the availability of vaccine through the Medicare demonstration.

- Demonstration projects were required to develop (or sustain) systems for influenza surveillance, systems to track usage of vaccine, systems for regular collection of information on mortality related to pneumonia or influenza and adverse medical events associated with influenza vaccination and systems of administrative records.

The cost-effectiveness study will be conducted using data maintained by the demonstration projects. Data will also come from HCFA and will include regular Medicare Part A and B claims, as well as vaccine claims submitted for payment under the demonstration. Annual beneficiary and nursing home surveys in all the demonstration areas will be used to estimate vaccination rates.

The TAG, which assisted with developing the demonstration design, will maintain oversight throughout the demonstration and cost-effectiveness evaluation projects.

Preparing for the First Year of the Demonstration

During 1988, HCFA and CDC worked to meet the mandated implementation date of October 1. HCFA and CDC entered into an inter-agency agreement in the Spring of 1988, sharing responsibilities for planning and monitoring the demonstration. CDC agreed to announce the availability of funds, purchase vaccine for the demonstration, review applications, process awards and assist the demonstration sites. HCFA funded CDC's activities through a first-year transfer of $3.3 million to cover administrative costs and the bulk purchase of 305,000 doses of vaccine. In addition, HCFA agreed to design the demonstration, design a claims payment system, provide technical assistance to the sites and prepare the required Reports to Congress. HCFA engaged the services of a contractor, Abt Associates Inc., to provide technical assistance to the sites and conduct the first two annual influenza vaccination surveys. HCFA also selected a single carrier to process claims under the demonstration.

During the summer of 1988, CDC arranged a bulk purchase of influenza vaccine for the demonstration. As a buyer in a market served by a small number of large producers, CDC was at a competitive disadvantage, having to accept a minimum order of 424,300 doses to complete the purchase. In November, 200,000 doses of influenza vaccine were distributed to the nine sites or released for other uses. The balance of the order that was purchased, but not distributed, was sold to Sweden or destroyed.

Planning and awarding the demonstration cooperative agreements required nearly 9 months. Design activities began in the Spring of 1988 and culminated in an accepted demonstration design in May. The demonstration was announced in the Federal Register on July 14, 1988 (FR Doc.88-15854); applications were reviewed in September; and award letters mailed in October. Nine sites received a total of $2.7 million in the first year. The sites are as follows:

- **Arizona** (Maricopa County Department of Health Services);
- **Massachusetts** (The Massachusetts Department of Public Health);
- **Michigan** (The Michigan Department of Public Health);
- **New York** (The University of Rochester Department of Preventive Medicine);
- **North Carolina** (The North Carolina Department of Human Resources);
- **Ohio** (The Ohio State Department of Health);
- **Oklahoma** (The Oklahoma State Department of Health);
- **Pennsylvania** (The Allegheny County Health Department); and
- **Texas** (The San Antonio Metropolitan Health District).

First Year Experiences

During the time period from October 1988 through September 1989, the nine demonstration projects developed or enhanced influenza surveillance systems in intervention and comparison areas; developed beneficiary education and information materials and implemented outreach programs; designed and implemented procedures for collecting pneumonia and influenza mortality data and monitoring adverse medical events associated with influenza vaccination; and recruited and trained providers to administer vaccine, with particular emphasis on physicians and public health agencies. Providers also began to administer vaccinations to eligible beneficiaries in November 1988, submitting claims for 26,000 vaccine doses administered during the 1988/89 season.

Although much was achieved, many of the projects encountered problems that delayed implementation. Most of the public health departments that administered the demonstration projects had valuable prior experience and networks of contacts with vaccine providers. None, however, had implemented an effort as large and as complex as the Medicare demonstration.

Most projects had to recruit new staff for the demonstrations. Because staff recruitment efforts could not begin until award letters were received, many sites experienced long delays coping with State and local hiring freezes and other barriers to achieving operational staffing levels. Most sites subcontracted certain components of the demonstration. Sites such as Michigan and North Carolina, in which State health departments had to develop working relationships with several county health departments, engaged in lengthy negotiations that delayed development of surveillance and other important data-collection systems.

Large numbers of participating vaccine providers, especially physicians and clinics, and eligible beneficiaries are crucial to the demonstration. Demonstration project managers had to overcome provider resistance to participating, due to the special demands of the demonstration such as added paperwork, new provider numbers and claims forms, a new and unfamiliar Medicare carrier and a requirement that physicians accept assignment of Medicare vaccine claims payments.

Projects were required to recruit physicians, nursing homes, clinics and hospitals as surveillance sites in both intervention and comparison areas. These sites report on the presence of flu-like illnesses and submit cultures for laboratory tests to confirm the presence of influenza and determine its type. Implementation of surveillance systems was sometimes delayed by staffing and organizational problems, and by the need to train staff at sites that had no previous experience with rigorous disease surveillance methods.

Second Year Experiences

The nine original sites received approximately $3.6 million to conduct the demonstration during Year 2, which was from October 1989 through September 1990. In addition, in order to expend the full amount required, HCFA expanded the demonstration to four new statewide sites (Tennessee, Virginia, Indiana and Louisiana), and one new sub-State demonstration site in Illinois. Three of the four new States are informing providers that Medicare will be covering influenza vaccinations, but they are not implementing the other demonstration components, such as bulk purchase, beneficiary education and outreach. In addition, Tennessee has implemented an outreach program. In order to contribute to the cost-effectiveness evaluation, Illinois will function following the original demonstration model, with intervention and comparison areas. This site began operation in March 1990.

HCFA also funded a University of Michigan study of vaccine efficacy. This project utilizes case/control methodology to estimate the effectiveness of influenza vaccination in preventing hospitalization for pneumonia and influenza among institutionalized and noninstitutionalized elderly beneficiaries in Michigan. Data collection for this study began in January 1990.

Vaccine claims submitted by the nine original sites increased dramatically in Year 2. By the middle of April 1990, 457,000 claims had been submitted. The four new statewide sites also generated a high volume of activity, with 359,000 claims submitted by the end of December 1989.

Demonstration projects increased the participation of providers and others in vaccine administration and influenza surveillance in the second year. Providers administering vaccine increased six-fold, from 476 in the first year to 3,100 in the second. Over 580 surveillance sites agreed to participate, of which physicians constituted the majority (515).

Status of the Cost-Effectiveness Study

In 1989, HCFA contracted with Abt Associates, Inc., to conduct the cost-effectiveness study. To estimate the effect of Medicare coverage, vaccination rates are being measured through annual surveys of beneficiaries and nursing homes for comparison between intervention and comparison areas. Also, vaccination rates in the three statewide sites that have not implemented outreach efforts will be compared to vaccination rates in intervention areas of the other demonstration sites to determine the effect of coverage, independent of outreach.

If influenza vaccination rates increase, they will generate savings for Medicare only if vaccinations reduce excess hospitalizations and mortality due to influenza and complications of influenza. Abt Associates and the University of Michigan will use data from the demonstration, combined with HCFA claims data as it becomes available, to test the effectiveness of vaccine in reducing hospitalization and mortality.

The chief benefits resulting from Medicare coverage of influenza vaccine are expected to be: 1) a reduction in Medicare hospital admissions for pneumonia and influenza(P and I) and a consequent reduction in Medicare hospital payments; and 2) a decline in mortality related to P and I. The primary cost of the benefit to the Medicare program is, of course, the added outlay for influenza vaccine and for its administration. The overall strategy for the evaluation is to estimate the benefits of vaccine coverage by comparing annual outcomes (Medicare P and I hospital admissions, Medicare outlays, deaths related to P and I) between intervention and comparison areas. The expected cost of vaccine coverage hinges for the most part on the number of Medicare beneficiaries who would seek to be vaccinated if influenza vaccine became a covered benefit. The survey of beneficiaries will be conducted in each year of the demonstration in order to estimate the effect of vaccine coverage on beneficiary vaccination rates.

In order for Medicare coverage to be effective the following must occur:

- vaccination rates must increase in intervention areas relative to comparison areas after coverage;
- hospitalization and death rates related to influenza must be lower for vaccinated beneficiaries: higher vaccination rates must lead to fewer hospitalizations and fewer deaths; and
- total Medicare coverage costs must be less than total Medicare payments saved (through reduced hospital and other outlays).

The evaluation will determine the following cost-effectiveness ratios:

- o Medicare coverage costs per reduced hospitalizations;
- o Medicare coverage costs per reduced deaths; and
- o Medicare coverage costs per reduced Medicare payments.

In the first year of the demonstration, 17,000 Medicare non-institutionalized beneficiaries in the nine demonstration sites were interviewed by telephone to determine influenza vaccination

Rates were higher than expected, averaging 43 percent and ranging from 37 to 56 percent. A survey of nursing homes showed a range of estimated vaccination rates (66 to 82 percent) among institutionalized Medicare beneficiaries.

Sufficient data from the demonstration projects are not yet available to support a rigorous estimate of the cost-effectiveness of a Medicare benefit. The analysis of the Medicare medical claims for the second year of the demonstrations necessary to evaluate the cost-effectiveness will not be completed until the Summer of 1991.

Conclusions

The Medicare influenza vaccination demonstration should be extended for an additional 2 years, because data are not yet available to support a valid estimate of the cost-effectiveness of a Medicare influenza vaccine benefit. Given the vagaries of influenza and the related annual variations in outcome measures, the inclusion of the 2 additional years may permit determination of the sensitivity of cost-effectiveness estimates.

The Secretary will submit the final Report to Congress by April 1, 1993.

I. INTRODUCTION

The Omnibus Budget Reconciliation Act (OBRA) of 1987 mandated a demonstration to determine the cost-effectiveness of providing influenza vaccine as a covered benefit for Medicare beneficiaries. This report describes steps the Health Care Financing Administration (HCFA), working cooperatively with the Centers for Disease Control (CDC), have taken to implement the demonstration and complete the study of cost-effectiveness.

This chapter summarizes the legislative background of the demonstration and reviews previous research on the nature of influenza, the efficacy of influenza vaccine, the health-related outcomes of vaccination and vaccine use among the elderly.

Chapter Two describes the demonstration design that was adopted by HCFA and CDC, in consultation with a panel of experts.

Chapter Three documents the achievements and difficulties of HCFA, CDC, and the demonstration sites during the first 2 years of the Medicare influenza vaccine demonstration. As discussed in this chapter, the pace of implementation was slowed by a series of practical problems encountered at Federal, State and local levels of government. Some sites used subcontracting arrangements between grantees and county health departments. These arrangements provided a valuable infrastructure for distributing vaccine, but staff lacked experience with projects as large and complex as the Medicare demonstration.

Chapter Four describes the process and planned analyses HCFA and CDC have developed for evaluating the demonstration and estimating the cost-effectiveness of a Medicare influenza vaccine benefit. This chapter also presents the results of baseline surveys of Medicare beneficiaries and nursing homes to determine vaccination rates in the demonstration sites.

Chapter Five summarizes lessons learned in the first 2 years of the demonstrations that support a recommendation to extend the demonstration for an additional 2 years.

A. Legislative Background

Under the terms of section 4071 of OBRA 1987, influenza vaccine will be a covered Medicare benefit on November 1, 1990, if the Secretary of Health and Human Services determines that influenza vaccination is cost-effective, based on information from the first 2 years of the demonstration (to be implemented by October 1, 1988, continuing for 2 years). In support of the Secretary's finding, a preliminary Report to Congress is due by October 1, 1990. If the Secretary finds that data are insufficient for a finding on cost-effectiveness by October 1, 1990, the demonstration must continue for an additional 2 years. After this additional time, the Secretary must submit a final report no later than April 1, 1993. Unless findings of the study indicate that a benefit will not be cost-effective, coverage will be extended to all eligible beneficiaries no later than 1 month after submission of the Report.

OBRA required an expenditure of $25 million each year to cover the costs of vaccine and demonstration administration. In addition, certain conditions regarding the Secretary's finding on cost-effectiveness were included:

- the Secretary must consider direct cost of the vaccine, utilization of the vaccine that might otherwise not have occurred, costs of illness and nursing home days avoided, and other relevant factors; and

- extended years of life for vaccinated beneficiaries, and the additional Medicare expenditures incurred during these years, is not to be considered to reduce the cost-effectiveness of the vaccine.

B. Influenza and the Medicare Population

Congressional legislation mandating the influenza vaccination demonstration for Medicare beneficiaries reflects a common belief (supported by a 1981 Office of Technology Assessment (OTA) study[1]) that the vaccine is cost-effective for the elderly. Influenza poses a clear but time-varying threat to the health of the elderly. There are, however, several factors that complicate the process of conducting a definitive analysis of the cost-effectiveness of Medicare coverage.

-- The nature and severity of this threat vary from season to season, reflecting the changes in host susceptibility and changes between or within seasons in the nature of the virus.

-- Measuring the extent and severity of influenza depends on the quality of surveillance systems (which is uneven) and the skills of investigators who have, in the past, often disagreed on the most appropriate ways to combine and analyze the pertinent data.

-- The health-related outcomes of vaccination depend on clinical efficacy, the ability of responsible authorities to match the type, timing and amount of vaccine produced to the season's needs, the willingness of providers to recommend vaccination, and the willingness of the public to be vaccinated.

-- Demonstrating the total cost-effectiveness of influenza vaccine is not the same as demonstrating the cost-effectiveness to Medicare of an influenza vaccine benefit. In the long run, beneficiaries who formerly paid for their own vaccinations will likely have Medicare pay, limiting any net increases in vaccination rates.

This section discusses in greater detail evidence from previous work on the outcomes and cost-effectiveness of influenza vaccination programs.

---

[1] OTA. Cost-Effectiveness of Influenza Vaccination. Washington, D.C., December, 1981.

1. Variation in Influenza Prevalence and Severity

Influenza is an infectious, viral disease that affects the U.S. population, to a greater or lesser degree, every winter. In some years, influenza reaches epidemic proportions; that is, morbidity and mortality due to influenza greatly exceed that in years when little influenza activity occurs. Influenza epidemics present considerable variation across time, geography, and severity among different subgroups in the population.

The elderly suffer most from influenza, through relatively high rates of hospitalization and mortality. Barker (1986) used national mortality and hospitalization data to study five epidemic periods and three comparable nonepidemic periods during the 1970s. He estimated that excess hospitalizations among the elderly during influenza epidemics averaged 1,213 per 100,000 population.[2] Rates were lower for younger persons, but epidemic thresholds were exceeded in all age ranges during the 5 years. In addition, Barker found significant excess hospitalizations for other respiratory and cardiac diagnoses during influenza epidemics, particularly among the elderly.

During the same 8 year period studied by Barker, the CDC estimated that influenza contributed to approximately 127,000 excess deaths, largely among the elderly.[3] Couch et al. (1986) studied age-specific hospitalization and death rates during influenza epidemics in Houston. Hospitalization rates ranged from 60 per 100,000 each year for 5-54 year olds to 430 per 100,000 each year for those over 65 years of age. Fewer than 3 deaths per

---

[2] Barker, W., "Excess Pneumonia and Influenza Associated Hospitalization During Influenza Epidemics in the United States, 1970-1978," American Journal of Public Health, 1986, (76), 7, p. 761.

[3] OTA, p. 53.

100,000 population were due to acute respiratory disease among the 5-54 year olds, but 76 deaths per 100,000 were experienced by the over 65 group.[4] Glezen (1982) also found that there may be an age shift during a given epidemic, with early spread of influenza in the community concentrated among school-aged children, particularly those aged 10-19.[5] Indeed, epidemics beginning in December seem to pause during school vacation and return in a diminished form when school resumes. The role of school children in amplifying an epidemic has led the Japanese to vaccinate school children as opposed to the U.S. practice of vaccinating those most at risk for serious sequelae following infection.[6]

Lui and Kendal (1987) studied mortality during influenza epidemics from 1972-1985. They found that about 80-90 percent of all influenza-associated deaths were in persons over 64 years of age. They estimate that influenza-associated mortality averaged 41 per 100,000, but varied considerably from year to year. In addition, epidemics displayed regional variation. For example, the epidemic of 1974-75 had a relatively low impact on mortality in the New England and Mid-Atlantic States, and the 1979-80 epidemic had an extremely low impact in the sunbelt States.[7]

---

[4] Couch, R. et al., "Influenza: Its Control in Persons and Populations," Journal of Infectious Diseases, 1986, 153:3, p. 431.

[5] Glezen, P., "Serious Morbidity and Mortality Associated with Influenza Epidemics," Epidemiologic Reviews, 1982, Vol. 4, p. 25.

[6] Oya, A., Nerome, K., "Experiences with Mass Vaccination of Young Age Groups with Inactivated Vaccines," Options for the Control of Influenza, 1986, p. 183.

[7] Lui, K. J. and Kendal, A., "Impact of Influenza Epidemics on Mortality in the United States from October 1982 to May 1985," American Journal of Public Health, 1987, (77)6, p. 712.

Antigenic Drift and Antigenic Shift

The variation in epidemic severity across time, region and age cohorts reflects host susceptibility (discussed below) as well as the changing nature of the influenza viruses. There are two prominent types of influenza virus, A and B. Type A viruses show substantial antigenic variation, with 13 hemagglutinin antigenic subtypes (H1 - H13) and 9 neuraminidase subtypes (N1 -N9) that do not cross-react with each other; that is, antibody response to one hemagglutinin subtype will offer little or no protection against another. Viral strains, the products of antigenic drift, are commonly referred to by the year and place of discovery. For example, A/Hong Kong/68(H3N2) is type A, subtype H3N2, strain Hong Kong, discovered in 1968.

Antigenic Drift

Changes within a subtype are caused by subtle mutations in the genetic material of the virus. Mutations in virus subtypes are known as antigenic drift; the same subtypes are arrayed, but with a slight mutation in one or more subtype, causing a new strain to develop. Antigenic drift occurs continually. For example, the original strain of type A, subtype H3N2 influenza was isolated in Hong Kong in 1968 and is called A/Hong Kong/68(H3N2). Virtually all strains isolated worldwide during the subsequent 3 year pandemic were serologically identical. After that, antigenic drift produced other H3N2 strains with minor differences, several of which caused epidemics over the next 15 years.

Mutated subtypes are more likely to infect because many people will not mount an effective antibody response, having never encountered them before. In some cases the new "drifted" subtype is similar enough to its "parent" subtypes that individuals with antibodies to the parents will have some protection against the

"offspring." Some mutations can also cause a new carbohydrate to attach to surface proteins, masking the viral antigens so that an individual's antibodies cannot "recognize" the virus, even if it was encountered in the past. Both of these mutations increase the survivability of the virus.

Antigenic Shift

When two subtypes of influenza A coinfect the same individual, the potential exists for genetic reassortment of the multiple viral subtypes. Gene reassortment of the multiple hemagglutinin and neuraminidase subtypes and the eight individual segments of the viral genome allows new combinations of subtypes to arise. There are 256 possible combinations of RNA. The appearance of a reassorted virus is referred to as antigenic shift. These reassorted viruses appear at irregular and infrequent intervals, but are devastating when they do appear because virtually no one in the population has encountered them before, leaving the entire population vulnerable. The great pandemics of history were probably caused by reassorted or "shifted" viruses. In the 1968 pandemic, the new virus A/Hong Kong/68(H3N2) resembled the previous H2N2 subtype in all but one of the requisite eight genes. Only the H3 hemagglutinin was unfamiliar, although related to the H3 viruses present at the end of the 19th century. This seemingly slight reassortment was sufficient to cause one of the most severe pandemics of the past 50 years.[8]

Other severe epidemics are produced by the reappearance, after many decades of apparent dormancy, of a virus against which the younger members of the population have no immunity. These reappearances often manifest with distinctly age-specific attack

[8] Kendal, A., "Epidemiologic Implications of Changes in the Influenza Virus Genome," American Journal of Public Medicine, 1987, (82) suppl. 6A, p. 4.

rates. For example, the massive "swine flu" pandemic of 1918 caused the greatest morbidity and excess mortality among young adults. It is likely that much of the older population had been previously exposed to the same or an antigenically similar virus.

Host Susceptibility/Populations at Risk

Prevalence and severity of influenza epidemics reflect changes in the viruses themselves and previous exposure of the population. Prevalence and severity of clinical disease are also expressions of the health status of the population. The persons for whom vaccination is recommended by the CDC are those who are most likely to become severely ill after being infected with influenza or for whom upper respiratory illness has the most devastating consequences. The CDC's Immunizations Practices Advisory Committee currently recommends influenza vaccination for:

1) adults and children with chronic disorders of the cardiovascular or pulmonary systems that are severe enough to have required regular medical follow-up or hospitalization during the preceding year;

2) residents of nursing homes and other chronic-care facilities;

3) individuals 65 years of age or older who are otherwise healthy;

4) adults and children with chronic metabolic diseases, renal dysfunction, anemia, immunosuppression or asthma severe enough to require regular medical follow-up or hospitalization during the preceding year; and

5) children receiving long-term aspirin therapy, who may be at risk of developing Reye's syndrome following influenza infection.

Many Medicare beneficiaries fit into more than one of these categories, being elderly, chronically ill, institutionalized, or having been recently hospitalized.

Fedson and Kessler (1977) found that 30-40 percent of persons admitted to the hospital with respiratory conditions during influenza epidemics had been discharged from a hospital within the previous year.[9] In 1983, Harward et al. found that patients hospitalized during the autumn prior to contracting influenza were more likely to die from influenza than those with no history of recent hospital care.[10]

Nursing home residents and others in institutional settings are also more likely to contract influenza during an epidemic and more likely to become severely ill when they do. Arden et al. (1986) found that up to 60 percent of nursing home residents may be affected during an influenza outbreak, and up to 25 percent of these patients die or develop life-threatening complications. There is also evidence that vaccination of at least 80 percent of residents can confer protection on those residents who are not vaccinated; this is referred to as herd immunity.[11]

Glezen et al. (1987) found that the risk for acute respiratory disease is much higher in those with certain underlying conditions. These conditions include chronic pulmonary disorders, cardiac conditions, cancer and, to a lesser degree, other chronic conditions such as alcoholism and diabetes.

---

[9] Fedson, D., Kessler, H., "A Hospital-Based Influenza Immunization Program 1977-78," American Journal of Public Health, 1983, (73):422-445.

[10] Harward, M., Kaiser, D., Fedson, D., "Hospital-Based Influenza Immunization: Epidemiologic Rationale from the Shenandoah Study," Clinical Research, 1986.

[11] Arden, N., Patriarca, P., Kendal, A., "Experiences in the Use and Efficacy of Inactivated Influenza Vaccine in Nursing Homes," Options for the Control of Influenza, 1986, p. 155.

Finally, it is possible that the host-parasite relationship varies from one influenza epidemic to another. Kendal et al. note that "Even minor changes between influenza virus isolates can have dramatic consequences on such properties as receptor specificity, tissue tropism, host range and virulence."[12]

Morbidity and Mortality

To assess the timing, prevalence and severity of an influenza epidemic, valid measures of excess morbidity and mortality are needed. There are several measures that researchers have proposed. Lui and Kendal used cyclical regression models applied to national vital statistics from a 13-year period to estimate baseline mortality in nonepidemic years.[13] Alternatively, Kendal et al. suggest selecting a year when very little influenza was reported, for use as a baseline for comparison purposes.[14] Glezen suggests that summertime influenza mortality and morbidity are perhaps better baseline measures against which to estimate wintertime influenza-related events.[15]

Beyond the issue of how to estimate baseline and "excess" morbidity and mortality, there is the question of how to define influenza-related health events. Glezen chose hospitalizations for acute respiratory illnesses to estimate the morbidity impact of influenza epidemics.[16] Barker used data on hospitalizations for

---

[12] Kendal, A. et al., "The Effect of Influenza Virus Genetic Alteration of Disease in Man and Animals," Banbury Report 22: Genetically altered virus and the Environment, New York: Cold Spring Harbor Laboratory, 1985, p. 119.

[13] Lui and Kendal, pp. 714, 715.

[14] Kendal, A. et al., p. 120.

[15] Glezen, p. 33.

[16] Glezen, p. 26.

pneumonia and influenza (P and I), other respiratory tract conditions and acute cardiac conditions obtained from the National Hospital Discharge Survey.[17]

To capture mortality related to influenza, Lui and Kendal compared P and I deaths and total excess deaths during influenza epidemics. They found that there was not a constant relationship between the two. For example, measuring excess P and I deaths alone indicated that the 1975 A/Victoria epidemic was the most severe in the past 15 years. In contrast, total excess death counts indicated that epidemics in the winters of 1978, 1979, and 1980 were actually more severe.[18] These authors suggested that, without laboratory confirmation, the decision to classify deaths as due to P and I is quite subjective, since such classification is more likely to happen during the winter and during publicized influenza epidemics than at other times.

Barker and Mullooly (1981) contend that pneumonia and influenza diagnoses fail to capture many deaths in which influenza played a contributing causative role. They found that, of 38 deaths among Health Maintenance Organizations (HMO) enrollees during two influenza epidemics, 32 death certificates mentioned P and I. Based on rules used for assigning cause of death, however, the National Center for Health Statistics would have counted 9 of 38 as P and I deaths; while the CDC, using their criteria, would have counted 23 P and I deaths.[19] Barker and Mullooly argue for including any deaths where P and I are contributing factors.

---

[17] Barker, p. 761.

[18] Lui and Kendal, p. 714.

[19] Barker, W., and Mullooly, John, "Underestimation of the Role of Pneumonia and Influenza in Causing Excess Mortality," Public Health Briefs, 1981, (71) 6, p. 643.

2. Surveillance Systems for Influenza Morbidity and Mortality

Measurement of morbidity and mortality related to P and I requires surveillance systems able to identify and accurately assign influenza diagnoses to cases. Surveillance systems can be classified as either passive or active. Passive systems rely on health care providers to report cases; there is no active surveying of providers or laboratories to identify cases. Active surveillance systems enlist providers to seek out cases and identify them with laboratory confirmation. Surveillance of influenza activity include the following national sources.

- Sentinel Physician Surveillance Network. Over 140 physicians report cases on a regular basis. A subgroup of approximately 40 physicians collect specimens from selected cases and submit these for laboratory testing. Culture confirmation identifies the type of influenza but not the subtype of influenza A.

- World Health Organization (WHO) Collaborating Laboratories. Over 50 laboratories based in State or local health departments, universities or hospitals report the number of specimens tested and the number and type of positive isolates for each week from early October through mid-May.

- Epidemiologic Surveillance Project. Case reports of culture-confirmed influenza are submitted electronically to CDC from State health departments in several States.

All three are CDC-operated systems that provide data from which decisions are made regarding the vaccine composition for the following year. Additional surveillance of the severity of an epidemic comes from the proportion of deaths associated with P and I reported from 121 cities each week throughout the influenza season.

3. Influenza Vaccine Efficacy

There are several different standards against which to measure the efficacy of influenza vaccines. Effectiveness in raising antibodies to a generally protective level, in preventing clinical symptoms, in preventing absenteeism or days lost from work, in preventing physician visits, or in preventing hospitalizations are all reasonable tests of vaccine efficacy. The following discussion of vaccine efficacy concerns inactivated vaccines, since these are the only vaccines approved for use in the U.S.

A number of studies have attempted to measure antibody levels following influenza vaccination. No single level of serum influenza hemagglutinin inhibition antibody can be chosen to indicate any specific index of immunity to a natural challenge. This is particularly true during the first appearance of a new major antigenic variant.[30] Numerous factors affect a vaccinated person's antibody response and, thus, affect vaccine efficacy. These factors include vaccine potency (amount of antigen), fit or match between vaccine components and wild virus, a person's prior exposures to influenza viruses, and the duration of immunity conferred by the vaccine.[31]

In terms of preventing absenteeism or lost work days, Oya and Nerome (1986) compared vaccinated Japanese school children with their unvaccinated peers in the same schools and day care centers. They found a clear difference in influenza attack rate and duration of illness, as well as absenteeism, between vaccinated and un-

---

[30] Ibid., p. 179.

[31] Ibid., p. 173.

vaccinated children. They also found evidence for some degree of herd immunity when 50-70 percent of children in a school were vaccinated. In addition, they observed that high vaccination rates appeared to delay, rather than prevent, influenza epidemics in schools.

In terms of preventing clinical symptoms of influenza, OTA reviewed 77 trials reporting vaccine effectiveness against naturally occurring influenza. The range of reported effectiveness for each virus type was 0 to 96 percent. The majority of trials reported effectiveness greater than 60 percent for homologous virus (identical to vaccine component) but more variable protection against heterologous (slightly dissimilar) wild viruses. Effectiveness was also summarized by population group studied and by vaccine dose. Factors that were found to affect vaccine effectiveness were remoteness of a population, attack rates of illness and general health of the population, dose of vaccine, interval between vaccination and challenge, and antigenic novelty of the virus.[22]

For the elderly population, who experience most of the excess hospitalizations and deaths due to influenza, vaccine effectiveness could reasonably be measured by the avoidance of severe illness. Barker and Mullooly studied four epidemics experienced by elderly members of an HMO. In two of the four, there was strong evidence for vaccine effectiveness in reducing P and I-associated hospitalizations and death, particularly among the elderly with high-risk conditions. There was no evidence, however, that influenza vaccine offered any protection against acute upper respiratory tract illness. The authors hypothesize that vaccine promotes circulating antibody and immunity protecting the lungs,

[22] Ibid., pp. 173, 174.

while providing little protection for the upper respiratory tract.[33] Montagne et al. (1983) found that previous natural exposure primed adults to mount effective antibody responses to vaccine antigens.[34] Arden et al. studied vaccine efficacy in nursing homes and found that although vaccine was only 30 percent effective in preventing illness, prevention of hospitalization and death was probably significantly higher.[35]

Vaccine Production

An effective vaccination campaign requires the timely manufacture and distribution of vaccine, the composition of which closely matches the predominant influenza strain. Each year WHO must make a recommendation regarding the composition of the trivalent inactivated vaccine to be prepared for the upcoming influenza season. Production of vaccine involves growing the virus in chick eggs and requires several months lead time to assure adequate supplies. The decision about vaccine composition must therefore be made by April 1 of each year to make vaccine available to the public in September and October.

The results of the WHO laboratory surveillance system as described above are used to identify emerging new virus strains and subtypes. Any strain that appears to be substantially new and different is likely to be included in the vaccine, even if outbreaks are not expected to be widespread, because the population in general has no pre-existing immunity to a new strain. In addition, a new variant can spread around the world in a matter of months, so that it is not possible to "watch and wait" through one

[33] Ibid., p. 179.

[34] Montagne, J. et al., "Summary of Clinical Trials of Inactivated Influenza Vaccine--1978," Review of Infectious Diseases, 1983, Vol. 5:4, p. 723.

[35] Arden, N. et al., p. 155.

season before making a decision on a new strain for the next year's vaccine.

During the 1988-89 influenza season, most H1N1 strains implicated in outbreaks resembled A/Taiwan/1/86[36] and the antibody induced by this vaccine component reacted well with the wild viruses. Nonetheless, the type B antibody in that vaccine reacted poorly with a newly emerging variant, identified in Asia. This new variant was labeled B/Yamagata/16/88. In addition, the H3N2 circulating virus more closely resembled A/Shanghai/11/87 than it did the existing vaccine strain of A/Sechuan/2/87. For these reasons, the 1989-90 vaccine was composed of type A(H3N2), A/Shanghai/11/87, type B/Yamagata/16/88,[37] and retained the type A (H1N1) component from the previous year.

The forecasting of the next year's strain must take place many months prior to the U.S. influenza season, and influenza itself can spread rapidly. It is therefore possible to make an informed prediction about influenza viruses, but fail to anticipate a significant new variant. In the case of antigenic shift, it may be very difficult to predict an entirely new subtype of virus, and harder yet to develop a vaccine against it in a short period of time. For these reasons, the vaccine is not always optimally matched to the wild viruses circulating in the U.S.

---

[36] New subtypes are generally labeled with the name of the discoveror or the city where discovery occurred, and the date (month and year) of discovery. A/Taiwan/1/86 is a Type A influenza virus, first identified in Taiwan, in January 1986. Recent vaccines have been trivalent, containing H1N1 (A) strain, an H3N2 (A) strain, and a (B) strain.

[37] National Centers for Disease Control, Morbidity and Mortality Weekly Report, March 24, 1989, Vol. 38, No. 11.

In some vaccine formulations, viral components have been difficult to grow in volume. In 1988, for example, production was delayed and many health care providers did not receive adequate supplies of vaccine until late October. Production volume is based on best estimates of need. A new strain against which much of the population is vulnerable is likely to cause a widespread epidemic and demand for vaccine will increase. It is not always possible, however, for vaccine manufacturers to correctly estimate the volume needs of the population and plan production accordingly. In the face of a severe and somewhat unanticipated epidemic, it is possible that sufficient supplies of vaccine would not be available. In such a situation, directing vaccine toward those most in need of protection becomes more important, but could also become more problematic.

Influenza vaccine is produced in the U.S. by four major manufacturers licensed to do so by the Food and Drug Administration: Connaught, Wyatt, Parke-Davis, and Evans Medical, Ltd. In response to recommendations on vaccine composition from WHO, these companies have generally produced from 20 to 24 million doses of vaccine each year. U.S. producers fill orders from CDC and from individual providers. They have also regularly supplied influenza vaccine to foreign markets. As noted, time is an important variable in making and distributing vaccine. Manufacturers make production plans in late spring, in order to meet distribution deadlines in August and September. The combination of limited competition, a worldwide market and severe time constraints on production and distribution tend to ensure a "seller's market" in influenza vaccine.

Vaccine Use Among the Elderly

As discussed above, CDC recommends that all persons over age 64, in addition to persons in any of the other risk groups, be vaccinated each year. Williams et al. assert that vaccination

rates in the appropriate groups are low.[29] In a study in Massachusetts, Abt Associates, Inc. found that little more than 20 percent of the recommended population were vaccinated.[30] OTA reports that each year during the 1970s, approximately 19 percent of the at-risk population were vaccinated.[31] In Allegheny County, Pennsylvania, where extensive promotion of vaccination has a long history, approximately 32 percent of the noninstitutionalized elderly were vaccinated in 1986.[32] During the extensive efforts made in 1976 (the so-called "swine flu program"), approximately 36 percent of the population was vaccinated.[33]

The determinants of vaccination rates are many and complex. CDC research indicates that an important factor in increasing vaccination rates is a physician's recommendation. Many physicians and their patients, however, appear to have misgivings about the safety and effectiveness of influenza vaccination.[33] CDC and the Fulton County Health Department surveyed elderly persons living in senior housing projects in Dekalb and Fulton counties, Georgia, in 1988. Of the 716 residents interviewed who were aged 65 years or over, 90 percent were aware of influenza vaccine, but 73 percent of these reported negative attitudes toward it, including misperceptions about efficacy or about the vaccine as a cause of

---

[29] Williams, W. et al., "Immunization Policies and Vaccine Coverage Among Adults: the Risk for Missed Opportunities," Annals of Internal Medicine, 108:616. .

[30] Abt Associates, Inc. Development and Evaluation of Health Education Intervention to Increase Adult Immunization Levels Against Specified Vaccine Preventable Diseases: Final Report. Centers for Disease Control, 1987.

[31] OTA, p. 27.

[32] CDC, Morbidity and Mortality Weekly Report, 1987, 36:617.

[33] Ibid., p. 617.

[33] Ennis, F. et al., Acceptance of Vaccination, Vaccines and Strategy, New York: Academic Press, p. 311.

influenza or other illness. The most important factor for determining vaccination was physician recommendation.[34]

Opinion Research Corporation conducted a survey of the general public for the CDC in 1981. They asked consumers about their vaccine-seeking behavior and found that perceived personal susceptibility to a disease and perceived likelihood of a local occurrence of a disease were important variables in determining use of vaccine. The perceived seriousness of the disease was also very important. Few respondents viewed influenza as being serious.[35] Many people incorrectly classify other viral diseases as "the flu," perhaps adding to the perception that influenza is not a serious disease.

Concern about side-effects of any vaccine will also prevent optimal utilization. The increased incidence of Guillain-Barre syndrome among vaccinated persons during 1976, and the resulting media coverage, seriously eroded public confidence in influenza vaccination.[36]

Influenza vaccination is generally a low-cost service, being free or very inexpensive in many settings (e.g., public health clinics, nursing homes, HMOs). Persons vaccinated during the course of an office visit for some other purpose usually have a small additional charge added to their bill. Although Medicare and

---

[34] CDC. "Adult Immunization: Knowledge, Attitudes and Practices--DeKalb and Fulton Counties, Georgia, 1988." Morbidity and Mortality Weekly Report, Atlanta: CDC, 1988, 37, pp. 657-661.

[35] Riddough, M. et al., "Factors Affecting the Use of Vaccines: Considerations for Immunization Program Planners," Public Health Reports, 1981, Vol. 96, No. 6, p. 528.

[36] CDC, "Public Attitudes Toward the Swine Flu Immunization Program and Media Coverage of Events: Some Valuable Lessons Learned," reproduced by National Technical Information Services, Department of Commerce, 1981.

many other third-party payors do not cover influenza vaccine, it is not clear that the cost of the vaccine is a barrier to access. If the experience with pneumococcal vaccine is any indicator, lack of insurance coverage is not a significant barrier. CDC notes that only 10 percent of the elderly report having received a pneumococcal vaccination, even though it is covered by Medicare."

[37] CDC. "Adult Immunization Knowledge . . .", p. 657-661.

II. THE DEMONSTRATION DESIGN

A. Design Issues

Within the broad OBRA guidelines, HCFA weighed various alternative designs for the demonstration.

- Should the design utilize random assignment of beneficiaries to treatment (receive vaccine under the demonstration) and control (do not receive vaccine) groups, or should comparisons of vaccination behavior and outcomes be made between groups with access to vaccine through the demonstration (the intervention group) and those served by different providers or living in different areas (the comparison group)? The former approach, an "experimental" design, reduces the chances of bias in estimating the effects of providing free vaccine, but raises ethical and practical questions (can different individuals served by the same physician be provided or denied free vaccine without generating resentment?). The latter "quasi-experimental" approach, while more prone to bias due to systematic differences between intervention and comparison groups, is a more practical alternative in many cases.

- How should vaccine administration be reimbursed under the demonstration? Should different rates apply to different types of providers? Should normal coinsurance apply? Should payment cover reasonable and customary charges, or be fixed?

- What entities should be eligible to apply for a demonstration cooperative agreement?

- How should a demonstration "site" be defined (geographical area, provider(s))? How large a target population will produce valid estimates of differences between intervention and comparison sites in vaccination rates and health outcomes? How should comparison sites be selected?

- How can the demonstration be designed to accommodate the "vagaries" of the flu virus, tendencies for the type and intensity of epidemic influenza to vary over time and among areas?

- In order to support a project evaluation and cost-effectiveness estimates, what kinds of data will be required, both from existing sources and from systems

established solely for the demonstration?

B. Development of Design Specifications

HCFA engaged the services of Dr. William Barker, an experienced physician and influenza researcher, to assist in designing the demonstration. Dr. Barker produced a document which formed the basis for HCFA's recommended demonstration design. With the concurrence of HCFA and CDC staff, and a TAG convened to review the design, a framework for the demonstration was established by the end of May 1988.

Demonstration Design. A quasi-experimental design, utilizing a concurrent comparison approach, was adopted. This meant that each demonstration site was to include an intervention area, within which influenza vaccine would be a covered service for Medicare beneficiaries eligible for Part B services, and a comparison area, not provided vaccine as a covered service under the demonstration.

Demonstration Sites and Providers. Three types of sites were suggested in the design document: metropolitan areas, complete States, and chains or cooperating groups of institutions. Cooperative agreement awards were made to applicants that proposed counties, groups of counties or States as sites. Medicare populations from 50,000 to 300,000 were deemed sufficient for valid estimates of the effects of the demonstration. Within each site, it was recommended that practicing physicians, public health departments, nursing homes, hospitals, and home health agencies be targeted for recruitment by demonstrations as vaccine providers.

Comparison Sites. Each demonstration was expected to select a comparison site, matched as closely as possible to the intervention site in terms of total population, the proportion of

the population eligible for Medicare, the total Medicare hospital admission rate and the percent of Medicare hospitalizations for P and I.

Payment. Payment to cover the costs of administering vaccine to beneficiaries enrolled in Part B of Medicare was fixed at two rates: $8.00 per dose for physicians and hospitals, and $4.00 per dose for health departments, HMOs and nursing homes. Vaccine acquisition for the demonstration was to be financed by the Federal Government through bulk purchase, described below. No deductibles or coinsurance would apply. Providers would be required to accept assignment for administering the vaccine.

Promotional Activities. Each site was required to implement programs of outreach and education to beneficiaries and providers in order to promote increased vaccination rates. This requirement serves one objective of the congressional mandate (making large amounts of vaccine available annually to Medicare beneficiaries) but complicates another (evaluating the effects of a Medicare influenza vaccine benefit). In fact, it would be difficult within this design to separate the effects on vaccinations of Medicare coverage from the effects of intensified outreach. To address this problem, HCFA extended coverage without the outreach requirement into three new statewide areas in the second year of the project, as discussed in Section 3.3 below.

Data Systems in the Demonstration Sites. Although maximum use was to be made of existing data collection systems, it was recognized that new or enhanced data collection capacity might be

needed in the sites to support the requirements for accountability and for an evaluation of the demonstration. Therefore each site was required to have or establish within the first year the following systems.

- **A clinical surveillance system:** This system would report flu-like illness from sentinel sites, such as physicians' offices, schools and hospitals, and would include a few providers that would obtain throat cultures and serologies. These specimens would be subjected to laboratory tests to confirm the presence of influenza and to determine its type. Clinical analysis was introduced into the design to contribute to the analysis of vaccine efficacy (which depends partly on a close match of vaccine to the prevalent flu strain) in the presence of variation in strains among areas and between flu seasons. Surveillance is expected to be conducted in intervention and comparison areas throughout the influenza season.

- **A vaccine tracking system:** Demonstration projects were required to maintain predemonstration levels of vaccine purchase and use in order to reduce the substitution of Medicare-financed vaccine for stocks of vaccine customarily purchased. In addition, each site was required to monitor the amounts of vaccine used and the amounts remaining at the end of each flu season.

- **Vital statistics and adverse events data:** To support the evaluation of the effect of vaccination on mortality outcomes in the demonstration, sites were expected to design systems to collect information from State vital statistics departments on the numbers of deaths, in intervention and comparison areas, for which pneumonia or influenza was an indicated cause of death. Sites were also expected to monitor adverse medical events associated with influenza vaccination.

- **Administrative records:** Sites were required to maintain records of their activities related to provider recruitment, beneficiary outreach and vaccine distribution.

C. The Role of the TAG

A TAG was appointed to review the draft demonstration design. HCFA plans to convene the TAG periodically during the demonstration. The group will be asked to review the evaluation design proposed by HCFA's evaluation contractor. The evaluation is discussed further in Chapter 4. The TAG will also review major deliverables including a preliminary cost-effectiveness analysis and the final report of the evaluation.

Other TAG responsibilities will include review and monitoring of other HCFA studies involving influenza vaccination. In particular, it is expected that a subcommittee of the TAG will work with the awardee HCFA has selected to conduct a study of vaccine efficacy (see Section 3.3).

D. Consideration of Data Collection for the Cost-Effectiveness Study

HCFA, CDC and HCFA's technical assistance contractor, Abt Associates, Inc., shared responsibilities for assisting the demonstration projects implement data collection procedures. Upon award of the cooperative agreements, all projects were required to submit operational protocols. Protocols addressed the following topics:

-- demonstration design: intervention/comparison areas, staffing plans and provider vaccine administration goals;

-- provider recruitment and provider relations: pre-demonstration immunization practices, approaches to identifying, recruiting and maintaining ongoing communication with providers;

-- information and education: description of the project's "message," method, and plans for targeting outreach to high-risk beneficiaries;

-- vaccine distribution and accountability: methods for documentation, plans for vaccine distribution (ordering

procedures, tracking, storage)

-- surveillance activities: current surveillance activities, plans for expanded community and hospital surveillance, surveillance time frames, subcontracting arrangements, methods of reporting culture test results;

-- laboratory processing of specimens: methods for distributing test materials, plans for testing, schedules for delivery and processing of specimens;

-- monitoring mortality due to P and I: process for obtaining vital statistics, schedule and timing of reports;

-- adverse reactions monitoring: methods, instruments; and

-- claims processing: methods for educating providers about claims processing, methods for monitoring providers (assuring each vaccination yields a claim, assuring recipient eligibility, assuring claims directed to demonstration carrier, assistance for providers with excess denials).

Each project was instructed to include copies of forms that would be used for collecting demonstration data and tracking vaccine utilization. HCFA reviewed and approved all projects' educational and promotional materials.

CDC developed a reporting format for all projects. Projects were instructed to supply quantitative information on a quarterly basis covering: numbers of providers and doses of vaccine administered; numbers of participating surveillance sites, by type and function (reporting absenteeism, reporting flu-like illness); providers submitting influenza culture and/or serology specimens; reported numbers of adverse events; and "vaccine accountability" data (doses received, distributed, inventoried, lost or wasted).

The Government and the technical assistance contractor have assisted the demonstration projects on an ongoing basis, beginning during development of operational protocols. As expected, some projects have needed less help than others in adapting to the reporting requirements of the demonstration. Collection of valid data is crucial for the cost-effectiveness study. Therefore, monitoring of project performance will continue throughout the demonstration.

III. IMPLEMENTATION AND OPERATION OF THE DEMONSTRATION

In order to implement the demonstration and support the study of cost-effectiveness, HCFA concluded an inter-agency agreement with CDC. Both agencies worked toward the mandated implementation date of October 1, 1988, conscious of two major objectives:

- procure and distribute large amounts of vaccine for Medicare beneficiaries, with an annual expenditure of $25 million for the demonstration; and
- design and implement a demonstration claims processing and data collection system to pay claims and to facilitate a study of the cost-effectiveness of a Medicare influenza vaccine benefit.

The October 1988 implementation objective was not fully realized. Problems encountered at various stages by Federal, State, and local authorities delayed the project. Installation of structures and processes for collecting data was delayed. The amount of vaccine administered to eligible beneficiaries under the demonstration in the first year fell short of expectations.

This chapter describes the planning and implementation phases of this demonstration, as well as the achievements and problems of the first 2 years.

A. Preparing for the First Year of the Demonstration

1. Overview

In response to the congressional mandate in OBRA (December 1987), HCFA and CDC began planning to implement the demonstration. To understand developments in the first year, it is important to have an appreciation for relationships in the timing of events.

Exhibit 1 depicts the relationship between planning and other tasks required to prepare for the demonstration, and the annual cycle of influenza and influenza vaccination activities. Pre-demonstration tasks included:

Congressional mandate:	December 1987
Design development:	January through April 1988
TAG design approval:	May 1988
Vaccine purchased for the demonstration:	June through August 1988
Program announcement:	July 1988
Grant proposal review:	September 1988
Award letters:	October 1988
Vaccine delivered to demonstration sites:	November 1988

HCFA and CDC recognized that these necessary startup tasks would limit vaccine distribution during the first year of the demonstration. To understand why, it is instructive to view this chronology in the context of the natural annual cycle of influenza and influenza vaccination in the United States.

- Vaccine is made available by manufacturers by the end of August and distributed by September.

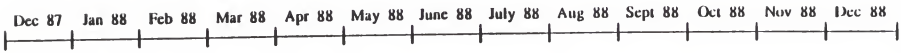
- The "optimum" vaccination period, as recommended by CDC, is between September and November to ensure time for antibodies against influenza to develop in vaccinated individuals.

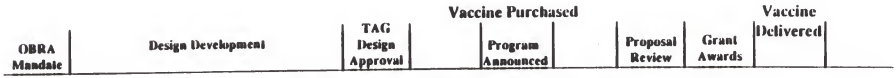
- Influenza epidemics usually begin in November and continue through March or April, the period during which surveillance should occur.

Faced with staffing and organizational demands, the demonstration projects were unprepared to conduct full-scale surveillance efforts during the 1988-89 influenza season. In addition, because of the time required for the steps that precede making competitive awards, the demonstration projects lost 2 critical months (September and October) of the "optimum" vaccination period in the first year.

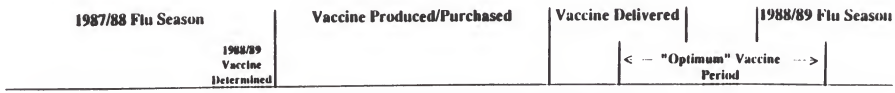
Exhibit I
Medicare Influenza Vaccination Demonstration Cost-Effectiveness Study

Schedule of First Year Implementation Activities

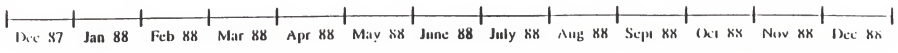




Medicare Demonstration Project Schedule



Influenza and Influenza Vaccination Annual Cycle



2. Project Management Responsibilities

After meeting in February 1988, HCFA and CDC executed an intra-agency agreement to implement the demonstration. HCFA transferred $3.3 million to CDC to fund its activities during Year 1, which included:

- developing and publishing a Federal Register announcement about the availability of funds to implement the demonstration;
- awarding the first-year vaccine purchase contract;
- reviewing applications and processing the Notices of Awards to the demonstration sites; and
- providing technical assistance and monitoring the implementation plans of the demonstration sites.

HCFA accepted the following responsibilities:

- developing the demonstration design;
- paying the providers for the administration of the vaccine and arranging for the processing of vaccine claims;
- providing technical assistance to the sites; and
- preparing and submitting the congressional reports.

HCFA secured additional assistance by contracting with an influenza research expert, Dr. William Barker, to develop the demonstration design and, also, by engaging the services of Abt Associates, Inc., to provide technical assistance to the sites during the implementation of the demonstration and to complete the study of cost-effectiveness for the mandated congressional reports.

3. Bulk Vaccine Acquisition

In Section 4071 of OBRA 1987, Congress authorized the Secretary to purchase influenza vaccine in bulk for the demonstration and to distribute it in a manner to make it widely available to Medicare beneficiaries. Under the intra-agency agreement, CDC was given responsibility for purchasing vaccine for the demonstration, because of its existing vaccine purchase program and its knowledge of the production and distribution system.

As described in Section 1.2, influenza vaccine production is highly concentrated in a small number of firms. Vaccine production must conform to demanding time constraints, between the time when the following season's vaccine type is determined (March) and the time when the vaccine is needed, to be optimally effective (between September and November). This combination of factors increases the vaccine producers' ability to demand favorable contractual conditions, such as minimum lot sizes.

In the summer of 1988, HCFA and CDC agreed that 250,000 doses of influenza vaccine would be needed for the first year of the demonstration. CDC solicited bids from the major manufacturers of vaccine. None were willing to sell the Federal Government less than a one-lot quantity (424,300 doses). The Federal Government finally reached an agreement with Connaught Laboratory, Inc., to purchase a single lot, at $1.377 per dose. Connaught arranged to fill an order for roughly 120,000 doses in Sweden and, thus, was able to reduce the Federal Government's contractual requirement to 305,000 doses. Total Federal expenditure of approximately $400,000 was well below the goal of $3.5 million for annual vaccine purchase announced in the Federal Register.

The manufacturer shipped 200,000 doses directly to the demonstration projects late in the fall of 1988. The remaining 105,000 doses were considered "excess government property," because

they were made available very late in the flu vaccination period. These excess doses were offered and distributed to immunization programs outside the demonstration areas. No records of how many Medicare beneficiaries might have received them are available.

.4. Site Selection

CDC's announcement of the demonstration in July 1988 stated the purpose of the demonstration (to assess the cost-effectiveness of a Medicare influenza vaccine benefit) and eligibility requirements for applicants:

- public health agencies or other public or nonprofit entities;
- priority given to areas with established immunization delivery programs and large Medicare populations to maximize vaccine distribution to the target population.

The announcement also stated that approximately $6.5 million would be available for the first year of the demonstration, with $3.0 million to support administration of up to nine demonstration sites and $3.5 million in "direct assistance vaccine to be provided in lieu of cash."

Applicants were instructed to include provider recruitment plans in their proposals, focused on private physicians and public health department clinics as primary providers of vaccine, with recruitment of secondary providers, such as nursing homes, hospitals and HMOs encouraged. Applicants were provided with the demonstration design. Some addressed design features in their proposals, specifying candidate comparison areas.

After a 1-month application period, CDC and HCFA staff met on September 15, 1988 to review the 16 submitted proposals. Nine sites were selected for awards, totalling $2.7 million in the first year.

Arizona (Maricopa County Department of Health Services) was awarded $157,000 for Year 1. The intervention area is Maricopa County, with Medicare Part B enrollments of 222,000.[35] Pima County is the comparison area, with 76,000 Part B enrollees. Both areas are highly urbanized; the intervention area is more urbanized than the comparison area (95 percent urban, compared to 88 percent).

Massachusetts (The Massachusetts Department of Public Health) was awarded $215,000 for Year 1. Essex County is the intervention area, with 91,600 Medicare Part B enrollees. Worcester County is the comparison area, with 95,200 Part B enrollees. The intervention area is more urbanized than the comparison area (90 percent, compared to 72 percent).

Michigan (The Michigan Department of Public Health) was awarded $483,000 for Year 1. The intervention area includes Calhoun, Ingham, Jackson, and Kalamazoo counties, with Medicare Part B enrollments of 93,300. The comparison area includes Kent, Muskegon, and Ottawa counties, with Part B enrollments of 87,800. Both areas are equally urbanized (72 percent urban for the intervention area, compared to 73 percent for the comparison area).

New York (The University of Rochester Department of Preventive Medicine) was awarded $478,000 for Year 1. Monroe County is the intervention area, with Medicare Part B enrollments of 990,000. Onondaga County is the comparison area, with 58,700 Part B enrollees. The intervention area is slightly more urbanized than the comparison area (88 percent, compared to 82 percent urban).

North Carolina (The North Carolina Department of Human Resources) was awarded $442,000 for Year 1. The intervention area contains 18 counties (Alexander, Burke, Caldwell, Catawba,

[35] Medicare Part B enrollments are for 1985.

Cleveland, Durham, Edgecombe, Franklin, Gaston, Johnston, Lee, Lincoln, Mecklenburg, Nash, Orange, Union, Wake, and Wilson), with Medicare Part B enrollments of 218,100. The comparison area includes Davidson, Davie, Forsyth, Guilford, Randolph, Rockingham, Stokes, Surry, and Yadkin counties, with Part B enrollments of 130,000. This demonstration is the least urban of the original nine sites, with the intervention area slightly more urbanized than the comparison area (60 percent, compared to 55 percent urban).

Ohio (The Ohio State Department of Health) was awarded $186,000 for Year 1. The intervention area is Stark and Summit Counties, with Medicare Part B enrollments of 120,300. Franklin County is the comparison area, with 92,800 Part B enrollees. Both areas are highly urbanized, but the intervention area is somewhat less so than the comparison area (84 percent, compared to 96 percent).

Oklahoma (The Oklahoma State Department of Health) was awarded $321,000 for Year 1. The entire State of Oklahoma is the intervention area, with Medicare Part B enrollments of 425,700. The State of Kansas is the comparison area, with Part B enrollments of 346,600. In both areas, roughly two-thirds of the population are urban.

Pennsylvania (The Allegheny County Health Department) was awarded $189,000 for Year 1. Allegheny County is the intervention area, with Medicare Part B enrollments of 226,100. The comparison area includes Lackawanna and Luzerne counties, with 108,700 Part B enrollees. The intervention area is more urbanized than the comparison area (96 percent, compared to 78 percent).

Texas (The San Antonio Metropolitan Health District) was awarded $195,000 for Year 1. The intervention area is Bexar County, with Medicare Part B enrollments of 99,800. Five Texas counties make up the comparison area (Travis, Williamson, Coryell, Bell, and

McLennan), with Part B enrollment of 89,200. The intervention area in Texas is more urbanized than the comparison area (95 percent, compared to 82 percent urban).

Table 1 presents additional comparative information relevant to selection of intervention and comparison areas. In addition to terms and conditions specific to each award, the Notice of Award contained the following terms.

- **Each site was given 30 days to identify intervention and comparison sites, matched across a range of measures that included geographical proximity, influenza prevalence in the previous season, influenza vaccination rates, Part B-eligible population, average Medicare expenditures per beneficiary, percent elderly and disabled population, urbanization of the area, demographic characteristics of the Medicare population, average income, hospital bed capacity, Medicare hospitalization rates, and last year's Medicare P and I hospitalization rate.**

- **Awardees were required to specify, in their information and education materials, that Medicare will be paying for the administration of influenza vaccine during the demonstration.** Insistence on this message reflected HCFA's concern that the nature of the intervention would not be understood by beneficiaries, thereby limiting increases in vaccination rates and compromising the research aims of the demonstration.

- **Awardees were required to provide all data needed by the technical assistance and evaluation contractors.** HCFA, CDC, and Abt Associates worked with the sites to define the kinds of data that would be required. HCFA and CDC designed a quarterly reporting format for each site, for recording data on vaccine administration, provider participation and surveillance.

B. First Year Experiences

During the first full year of the demonstration, the nine awardees accomplished many of their implementation objectives. Most developed or enhanced influenza surveillance systems in intervention and comparison areas. In many areas, there was no

Table 1
Medicare Influenza Vaccination Demonstration Cost-Effectiveness Study
SELECTED SITE DEMOGRAPHICS

SITE	POPULATION	% POPULATION NON-WHITE	% POPULATION URBAN	PER CAPITA INCOME	MEDICARE B ENROLLMENT	RATIO OF HOSPITAL STAYS TO ENROLLEES	% MEDICARE HOSP STAYS FOR PNEUMONIA
Arizona							
Intervention	1,846,600	5.3	95.2	$11,908	221,600	0.286	4.0
Comparison	585,900	6.7	88.3	$11,257	76,200	0.290	4.7
Massachusetts							
Intervention	650,400	2.3	90.1	$13,871	91,600	0.325	4.8
Comparison	655,500	2.1	71.6	$12,682	95,200	0.298	5.3
Michigan							
Intervention	791,700	8.1	71.6	$11,946	93,300	0.239	4.3
Comparison	768,900	9.8	72.8	$12,462	87,800	0.288	4.3
New York							
Intervention	704,900	11.7	88.2	$13,856	90,000	0.221	3.9
Comparison	465,300	8.3	82.4	$12,486	58,700	0.216	4.9
North Carolina							
Intervention	2,008,700	23.2	60.2	$11,071	218,100	0.243	5.5
Comparison	1,039,000	19.0	54.6	$11,236	130,000	0.264	4.8
Ohio							
Intervention	883,600	9.6	83.8	$11,297	120,300	0.329	4.6
Comparison	901,000	16.7	95.8	$12,048	92,800	0.323	4.0
Oklahoma							
Intervention	3,301,500	12.6	67.4	$10,736	425,700	0.129	6.2
Comparison	2,451,000	6.3	67.4	$12,511	346,600	0.141	5.6
Pennsylvania							
Intervention	1,388,300	11.1	95.6	$12,461	226,100	0.369	3.5
Comparison	555,700	1.1	77.6	$10,085	108,700	0.311	3.3
Texas							
Intervention	1,134,900	8.6	94.7	$10,047	99,800	0.297	4.4
Comparison	1,051,600	13.6	81.9	$11,824	89,200	0.269	4.7

• Data for the following are from 1985: Total population, Medicare B enrollment, Race, Per capita income. All other data are from 1986.
• Medicare enrollment figures for Kentucky reflect total Medicare (Parts A and B) enrollment. Figures for Part B only not available.
• Percent urban is calculated as the percent of the county population residing in a census designated urban area.
• DRGs 79, 80, 89 and 90 were used to calculate the percent of total Medicare hospital stays with pneumonia.
Source: AAI County Level File

prior history of systematic influenza surveillance. Project managers faced and generally overcame potential surveillance sites' unwillingness to participate and unfamiliarity with rigorous surveillance practice. Using a CDC format, projects developed forms and procedures for documenting adverse medical events that might be experienced by some recipients of influenza vaccination. Under HCFA and Abt Associates guidance, projects developed their own beneficiary outreach and information materials and began to publicize the demonstration to the target population of eligible beneficiaries. Project managers recruited and trained providers, concentrating on physicians and public health departments. Most sites were also successful in recruiting hospitals, nursing homes and other vaccine distribution sites.

1. Demonstration Vaccination Activity During the First Year

As discussed, vaccine distribution for the first year was not completed until November 1988, following award of the cooperative agreements in October. After receiving 200,000 doses of influenza vaccine in November, the nine demonstration projects distributed 103,000 doses of vaccine directly to participating providers, keeping roughly 97,000 doses as inventory. Providers submitted 23,000 vaccine claims during the first year of the demonstration, for an estimated total of nearly 26,000 doses administered. With the encouragement of Federal project officers, demonstration sites provided excess vaccine supplies to any interested parties.

Table 2 shows variation in vaccine usage among the demonstration projects in the first year. In two sites, Part B beneficiaries received nearly one-third of allotted doses: Arizona (29 percent) and Oklahoma (32 percent). In contrast, Michigan's Part B beneficiaries received 0.2 percent and North Carolina's received 1 percent of the demonstration vaccine.

Table 2

Medicare Influenza Vaccination Demonstration Cost-Effectiveness Study

Estimated Vaccine Usage for the First Year
(November, 1988 - March, 1989)

	DOSES DELIVERED TO SITE	DOSES DISTRIBUTED BY SITE TO PROVIDERS	DOSES ADMINISTERED TO MEDICARE PART B BENEFICIARIES	PART B BENEFICIARY DOSES AS PERCENT OF TOTAL DELIVERED
Arizona	25,000	20,016 **	7,341	29 %
Massachusetts	25,000	24,000 **	1,000	4
Michigan	20,000	4,000	334	02
New York	5,000	788	191	4
North Carolina	50,000	13,180	671	1
Ohio	10,000	8,630	2,000	20
Oklahoma	30,000	17,200	9,618	32
Pennsylvania	20,000	5,870	2,100	11
Texas	15,000	8,918 **	2,712	18
Total	200,000	102,602	25,970	13

* Includes intervention area and/or non-demonstration providers.

** Includes doses distributed to providers outside the intervention areas as excess Government property.

Source: Health Care Financing Administration

2. Implementation Issues

Although much was achieved, demonstration projects encountered problems that sometimes delayed their implementation plans. HCFA and CDC project officers and staff from HCFA's technical assistance contractor spent considerable time addressing these problems, in visits to the demonstration sites and in telephone and written consultations. In some cases, demonstration project staff lacked practical experience with some components of the design, such as targeted beneficiary outreach. Sharing experiences among the sites, at all-site meetings and through inter-site communications coordinated by Federal and contract staff, often proved helpful in these instances. In other cases, the size and complexity of a task simply required more time to accomplish than had been anticipated.

Organizational and Staffing Issues

State and local health departments were recognized as key to the success of the demonstration. In most cases, public health departments administer or cooperate in the administration of the demonstration projects. These agencies often have established vaccine delivery systems and valuable contacts with local providers and the vaccine industry.

Awardees, however, entered the first year of the demonstration with different amounts of previous experience with public vaccination programs, influenza and influenza surveillance methods, provider recruitment, and networking to accomplish public health objectives. Lack of experience may benefit or hinder demonstration objectives. On the one hand, sites with similar programs were able to achieve coverage implementation goals relatively quickly. On the other hand, the potential for studying the effect of Medicare coverage on vaccination rates may be greater in sites without well-developed public vaccination programs. (Nevertheless, baseline data from the beneficiary survey suggest that there may be little

difference among project areas in vaccination rates, as discussed later in Chapter 4.)

For example, the Pennsylvania project brought to the demonstration considerable previous experience in current public health outreach activity in Allegheny County. With respect to influenza, this project has been able to build on vaccination programs targeted to nursing homes and public health clinics, as well as established surveillance systems. In fact, because its existing programs have been so successful, Allegheny County has agreed to exclude nursing homes and clinics from demonstration outreach, targeting physicians and hospitals instead, to minimize the occurrence of large-scale substitution of Medicare-paid vaccinations for vaccinations previously funded from other sources.

In other project areas, previous efforts by public health agencies to promote influenza vaccination have been limited. In the San Antonio area, for example, public vaccine distribution before the demonstration was almost nonexistent; private physicians were the principal vaccine providers.

Most projects had to recruit new staff for the demonstration. Managers, however, were unable to begin the process of securing new positions, announcing openings and processing applications until after the award letters were issued in October. In some States, hiring freezes hindered project managers' flexibility even after awards were issued. The process of securing special approvals for demonstration positions consumed many months.

Organizational issues affected the pace of implementation. Sites varied in organizational complexity. Nonetheless, all were required to establish structures for the demonstration that had not previously existed.

For example, lacking direct ties to health care providers, North Carolina's Department of Human Resources expected to delegate most of the operational details of the demonstration to health departments in participating North Carolina counties. The counties, however, were not involved at the solicitation and award stage of the demonstration, and negotiations for county participation did not begin until the cooperative agreement was awarded. During negotiations, some counties resisted taking on new responsibilities. At the State and county levels, clearance procedures required to authorize new positions for the demonstration could not begin until the award was received and State/county negotiations had been concluded. Twenty new full-time equivalent positions were needed to augment existing staff to monitor project activities in the 27 participating counties. The process of negotiating subcontracts and staffing for the demonstration was not fully completed by the end of the first year of the demonstration.

Michigan also experienced significant implementation delays. The Michigan Department of Health submitted a proposal in collaboration with the University of Michigan, with a provision that the health departments of the seven intervention and comparison counties would participate as subcontractors. The State and the counties divided provider recruitment tasks: the State and university were expected to use their close ties, established through past research and vaccination education programs, to recruit and coordinate nursing homes while counties, with their knowledge of local medical communities, would coordinate the participation of hospitals and private physicians. Surveillance responsibilities were divided as well. The university has primary responsibility for surveillance in all areas, including lab testing, but county coordinators are expected to assist in

recruiting and monitoring surveillance providers. Because counties were not involved in the initial proposal, the time required for negotiating subcontracts to implement this system proved to take longer than expected.

Provider Relations

Providers, including physicians, hospitals, nursing homes and other health care professionals, and organizations, play a pivotal role in the demonstration. They administer vaccine, provided without charge by the demonstration through the awardee organization, directly to beneficiaries. Providers submit claims to Medicare's demonstration carrier for a fixed-rate payment to cover only vaccine administration costs.

There are several requirements in the demonstration that could limit widespread provider participation.

- Medicare providers must use provider numbers and a claim form that are unique to the demonstration.
- Claims must be submitted to a carrier that is different from the providers' usual carrier.
- Influenza claims must be separated from other claims if a beneficiary is both inoculated and provided other services in a single visit. A separate claim is required for each dose.
- Physicians must accept assignment of Medicare's payment for vaccine administration.
- Providers take on additional responsibility for keeping track of and reporting usage and inventory of vaccine.

All projects developed provider recruitment plans in their operating protocols, following Federal guidelines that stressed participation of private physicians and public health clinics. The pace of recruitment during the first year was affected by the extent to which awardees had cultivated productive relations with local providers and provider associations and the capacity of

project organizations to resolve contractual and administrative issues. The capacity of projects to fulfill recruitment goals and to retain provider participants from season to season during the demonstration will depend in part on conditions of the demonstration that affect all projects. For those physicians who do agree to participate in the demonstration, perceptions that reporting requirements are burdensome and claims payments are slow or subject to high denial rates could discourage continued participation.

As Table 3 shows, the demonstration projects recruited a total of 476 providers during the first year of the demonstration. As required, sites concentrated on involving physicians and public health departments. Most, however, also made some progress recruiting other providers. Texas and Ohio were most successful in recruiting physicians, whereas North Carolina and Oklahoma lagged in this area. There was no clearly "best" recruitment performance among all providers. Oklahoma and Ohio both recruited 123 providers, but Ohio's total included 103 physicians and no clinics, whereas Oklahoma recruited 75 clinics but no physicians.

Information and Education

Projects designed beneficiary information and education strategies both to communicate the message that Medicare would pay for influenza vaccine through the demonstration and to encourage beneficiaries to be vaccinated. As discussed, outreach should help clarify the intervention and promote vaccinations. Nevertheless, requiring intensive promotion of vaccine makes difficult the task of separating the effect on vaccination rates of Medicare coverage, as distinguished from outreach efforts. To address this problem, HCFA added four statewide sites in the second year, three of which will not develop special information and education programs. These additional sites are discussed in Section 3.3.2, below.

Table 3

Medicare Influenza Vaccination Demonstration Cost-Effectiveness Study

Provider Participation, Year 1

	PHYSICIANS	NURSING HOMES	HOSPITALS	PUBLIC HEALTH CLINICS	HHAs/VNAs	OTHER SITES	TOTAL
Arizona	40	3	3	1	1	0	48
Massachusetts	6	0	0	3	1	0	10
Michigan	12	0	0	2	0	0	14
New York	10	2	0	1	0	0	13
North Carolina	0	0	0	17	0	2	19
Ohio	103	6	13	0	0	1	123
Oklahoma	0	48	0	75	0	0	123
Pennsylvania	40	0	5	1	0	0	46
Texas	65	6	4	5	0	0	80
Total	276	65	25	105	2	3	476

Source: Health Care Financing Administration

As Table 4 shows, the nine original demonstration projects utilized a wide range of media for beneficiary outreach. Cooperation among sites in developing informational materials was facilitated by HCFA's technical assistance contractor. In addition to the general media categories shown in Table 4, sites also implemented hotlines, inserts for paychecks, pension checks, utility bills and grocery bags, special articles in journals targeted to the elderly, and mall clinics.

Influenza Surveillance

Surveillance data are needed to determine the nature, extent and severity of influenza epidemics in each demonstration area. A functioning surveillance system requires the participation throughout the flu season of many sites that report indicators of influenza and submit throat cultures and serology specimens for laboratory confirmation of influenza. Some sites, such as school systems and employers, report absenteeism during the influenza season. Others, including physicians, nursing homes, clinics and hospital outpatient departments, report numbers of influenza-like conditions encountered, on a regular basis, throughout the season. The demonstration utilizes a combination of community-based surveillance, located in physicians' offices and other sites that report cases and submit throat cultures, and hospital-based surveillance, from which serum samples are gathered.

Several projects encountered significant delays in the first year. In Michigan and North Carolina, the process of negotiating subcontracts with county agencies slowed the implementation of surveillance systems. In New York and Arizona, project administrators were unable to establish parallel surveillance systems in comparison areas. The remaining projects made good progress toward the goal of implementing parallel surveillance systems in intervention and comparison areas.

Table 4

Medicare Influenza Vaccination Demonstration Cost-Effectiveness Study

Information and Education

SITE	PRESS RELEASES & CONFERENCES		TV SPOTS/ INTERVIEWS		RADIO SPOTS/ INTERVIEWS		POSTERS & PAMPHLETS		SPEAKERS & PRESENTATIONS		BILLBOARDS/ BUSCARDS	
	Yes	No	Yes	No	Yes	No	Yes	No	Yes	No	Yes	No
Arizona*	X			X		X	X			X		X
Massachusetts	X		X		X		X		X		X	
Michigan		X				X	X			X	X	
New York		X	X		X		X			X		
North Carolina		X		X		X	X			X		X
Ohio	X		X		X				X		X	
Oklahoma		X	X		X		X			X		X
Pennsylvania	X		X		X		X		X		X	
Texas*	X		X		X		X			X		X
Total	5	4	6	2	6	3	9	0	3	6	4	4

* Bilingual (English and Spanish) materials available.

Source: Demonstration Project Operational Protocols, submitted annually by each awardee

Monitoring Mortality and Adverse Reactions Data

Mortality due to P and I is an important outcome measure in the cost-effectiveness study. State vital statistics provide the most reliable source of information on mortality by cause of death. Also, adverse reactions that lead to hospitalization are a cost of a vaccination program that will be taken into account in computing cost-effectiveness.

Projects accepted responsibility for securing information on mortality due to P and I in intervention and comparison areas and for monitoring adverse reactions of demonstration vaccine recipients. Most projects are collecting and reporting vital statistics data by age, underlying cause of death and county of residence. New York is also collecting information on co-morbidities, and Texas data indicate gender as well as age. In general, projects have arranged to access data from State vital statistics departments on a regular basis. Most will simply report total P and I deaths during each year of the demonstration. Massachusetts is building baseline vital statistics information for comparing trends in area P and I mortality during the demonstration.

Current demonstration data on mortality are not uniformly available because of implementation delays and the normal lags between the certification of death and the availability of reliable vital statistics data , which may be as much as 9 months. North Carolina's 90-day reporting lag is the shortest of all the projects.

Demonstration projects have instructed providers to report adverse medical events following influenza vaccination. Reactions serious enough to require medical intervention are rare. CDC has developed a common form that the demonstration projects are using

to document adverse events. This form records the individual's vaccination history, detailed clinical descriptions of illnesses associated with the most recent vaccination, and 7- and 30-day followup information. To date, no projects have reported any adverse events.

C. Second Year Experiences

1. Continuation of the Original Projects

In the second year of the demonstration, the original nine projects received continuation funding. Because of delays in implementation, six sites failed to spend all of their initial awards. Roughly $400,000 was carried forward from the first year, and $3.4 million in new Federal demonstration funds was made available. Table 5 shows total Year 2 funding, by site.

2. Expansion of the Demonstration

In addition to continuing the original nine sites, HCFA implemented four statewide sites in which Medicare paid directly for the vaccine and its administration. A second round of demonstration applications was solicited and reviewed, with the expectation that one or two awards would be made by 1990. Applications were also accepted from the demonstration sites for studies of vaccine efficacy.

Four Statewide Sites

Experience during the first year suggested that, even after all nine sites had implemented their programs, Congress' expectations regarding vaccine distribution might not be met. In addition, HCFA recognized that the evaluator of the demonstration

Table 5

Medicare Influenza Vaccination Demonstration Cost-Effectiveness Study

Year 2 Awards to the Nine Original Sites

GRANTEE	TOTAL YEAR 2 AWARD
Arizona	$ 299,859
Massachusetts	353,238
Michigan	581,841
New York	507,992
North Carolina	666,583
Ohio	277,704
Oklahoma	403,313
Pennsylvania	278,637
Texas	277,086
TOTAL	$ 3,646,253

Source: Health Care Financing Administration

would have considerable difficulty separating the effects on vaccination rates of Medicare's payment system from the effects of intensified beneficiary and provider outreach.

To address both concerns, HCFA selected carriers in four States (Tennessee, Virginia, Indiana and Louisiana) that were willing and able to begin paying claims for influenza vaccinations. In Tennessee, the carrier implemented a modest outreach program for beneficiaries, but in the other three States, the only feature of the demonstration design being implemented is provider payment. None of these sites will be required to set up surveillance systems or to monitor vaccine utilization. Vaccine purchases are made by providers, rather than by CDC.

Tenth Demonstration Site

HCFA and CDC agreed that funding at least one additional demonstration site would further project objectives. An announcement of HCFA's research priorities was placed in the Federal Register in May 1989. Two applications were received. Following their review, the application from the State of Illinois was accepted for funding, at a level of $366,000 in 1989/90.

Illinois' design follows the designs of the original nine sites with matched intervention and comparison areas. With nearly 166,000 Part B eligible beneficiaries in the intervention area, Illinois will field one of the larger demonstration projects. Illinois' award date was March 1990. This site should be operational and furnishing data during autumn of 1990.

Vaccine Efficacy Study

Vaccine is efficacious if it is matched appropriately to the prevalent strains of flu and confers some level of immunity to the disease. Neither the vaccine manufacturers nor CDC conduct annual

clinical trials to determine the efficacy of the vaccine produced for each season. The estimated cost-effectiveness of an influenza vaccine benefit may vary from season to season, depending upon how effectively vaccines immunize recipients against flu symptoms.

HCFA received proposals from two of the demonstration projects for studies to estimate vaccine efficacy. A proposal from the Michigan demonstration was accepted for funding in early 1990, at a 1-year level of $264,000. This study will be conducted using data from the 1989-90 flu season, with possible continuation funding for two more seasons. Michigan proposes to test the hypothesis that influenza vaccination will reduce the risk of hospitalization due to P and I during the flu season among noninstitutionalized elderly. A similar hypothesis will be tested with data from elderly in nursing homes.

A case/control design is proposed for the study of non-institutionalized individuals. Roughly 450 cases (elderly admitted to participating hospitals with a P and I diagnosis during the flu season) will be compared to two groups of controls: individuals hospitalized at the same time but not diagnosed with P and I, and individuals in the community with no records of recent flu-related hospitalizations. P and I diagnoses will be confirmed through lab tests. These data, together with detailed information on participants' vaccination histories, will allow researchers to compute the odds of a P and I attack, with or without a recent vaccination. Michigan researchers also plan to recruit approximately 10 nursing homes (1,000 residents) to conduct a similar efficacy study of the institutionalized population.

3. Second Year Activities

Entering the second year, the demonstration projects faced an influenza epidemic that promised to be more severe and widespread than the previous season. Vaccine distribution increased dramatically through expanded provider networks. Projects implemented data collection activities to describe and monitor incidence of the disease.

Vaccine Distribution and Claims Processing

HCFA and CDC anticipated increased vaccination activity in the second year of the demonstration. In the summer of 1989, CDC contracted to purchase 715,000 doses of vaccine, at $1.115 per dose. Table 6 shows the distribution among the nine original sites of the 317,000 claims submitted through the first week in January 1990.

Carriers in the four new statewide sites began processing claims in Autumn of 1989. As Table 7 shows, providers in these States had submitted 359,000 claims by the end of December 1989, showing that these sites are already making an important contribution to total vaccine distribution through the demonstration.

Some sites have reported claims processing problems encountered by providers. Complaints of long lags and payment errors reflect both provider unfamiliarity with the unique forms and provider numbers for the demonstration and carrier implementation problems. Both demonstration project managers and Federal Government project officers have begun to implement solutions, fully understanding that providers may refuse continued participation if these problems are not addressed.

Table 6

Medicare Influenza Vaccination Demonstration Cost-Effectiveness Study

Claims and Providers Submitting Claims, through 1/4/90

SITE	CLAIMS SUBMITTED	PROVIDERS SUBMITTING CLAIMS
Arizona	40,086	250
Massachusetts	10,353	131
Michigan	24,531	236
New York	9,712	150
North Carolina	39,053	226
Ohio	39,135	312
Oklahoma	91,768	1,234
Pennsylvania	41,944	290
Texas	20,301	278
Total	316,883	3,107

Source: Health Care Financing Administration

Table 7

Medicare Influenza Vaccination Demonstration Cost-Effectiveness Study

Statewide Medicare Influenza Vaccine Demonstration

Summary of Claims Processing Activities, through 12/31/89

STATE	TOTAL CLAIMS PROCESSED
Indiana	168,673
Louisiana	33,848
Tennessee	103,241
Virginia	53,027
TOTAL	358,789

Source: Medicare Demonstration Provider File

Provider Recruitment

In spite of some provider dissatisfaction with claims processing, demonstration projects have been able to support increased levels of vaccination activity because the numbers of participating providers have increased. Table 8 shows that all sites have been successful in recruiting physicians and public health departments, and most have added "secondary" providers, such as nursing homes and hospitals.

Total participation increased over six-fold, from 476 providers in the first year to over 3,100 in the second. All sites added physicians in the second year, achieving an overall increase from 276 to 2,300. Most sites involved at least one hospital in the demonstration. Only New York failed to recruit any hospital providers. As noted earlier, Pennsylvania excluded nursing homes and public health clinics to minimize the possibility that previous vaccination programs with these providers might "contaminate" the demonstration by shifting payments from other sources to Medicare. Oklahoma's statewide effort involved 1,200 providers in the second year, nearly 40 percent of the total for all nine States.

Influenza Surveillance

Both community- and hospital-based surveillance sites have begun to function during the 1989-90 season. Table 9 shows that all demonstration projects have established networks of sites in both intervention and comparison areas. Oklahoma leads in intervention sites (210), nearly one-half of the total (427). Two projects, Arizona and Michigan, have not succeeded in involving hospitals in surveillance activities. In general, however, counting only demonstration projects with hospital surveillance systems, a reasonable balance between intervention and comparison

Table 8

Medicare Influenza Vaccination Demonstration Cost-Effectiveness Study

Provider Participation, Year 2

	PHYSICIANS	NURSING HOMES	HOSPITALS	PUBLIC HEALTH CLINICS	HHAs/VNAs	OTHER SITES	TOTAL
Arizona	210	25	5	0	11	1	252
Massachusetts	76	38	8	14	10	4	150
Michigan	187	35	5	2	5	2	236
New York	120	28	0	1	1	0	150
North Carolina	160	37	4	1	23	1	226
Ohio	244	51	7	1	9	0	312
Oklahoma	816	270	54	74	21	0	1235
Pennsylvania	270	0	17	0	3	0	290
Texas	223	36	6	1	12	0	278
Total	2306	520	106	94	95	8	3129

Source: Health Care Financing Administration

Table 9

Medicare Influenza Vaccination Demonstration Cost-Effectiveness Study

Surveillance Participants
Year 2

	PHYSICIANS		HOSPITAL		TOTAL	
	Intervention	Comparison	Intervention	Comparison	Intervention	Comparison
Arizona	15	9	0	0	15	9
Massachusetts	12	8	3	3	15	11
Michigan	16	14	1	4	17	18
New York	5	4	4	2	9	6
North Carolina	122	52	0	0	122	52
Ohio	7	8	2	1	9	9
Oklahoma	202	27	8	9	210	36
Pennsylvania	8	0	3	1	11	1
Texas	14	12	5	2	19	14
Total	389	126	26	22	427	156

Source: Demonstration site records, through 2/9/90

areas has been achieved, with 26 hospitals participating in all nine intervention areas, compared to 22 in comparison areas. The apparent physician imbalance, 389 in intervention and 126 in comparison areas, is due in large part to North Carolina and Oklahoma in which physician surveillance sites make up 78 percent of the nine-project total (403 out of 515). The geographical scope of the Oklahoma and North Carolina demonstrations justifies numerous sites. Nevertheless, the fact that there are more sites reporting and submitting specimens in intervention than in comparison areas is cause for concern. Geographical imbalance could produce a distorted picture of a flu epidemic. With more reporting sites, an intervention area might appear to be involved in an epidemic earlier and with greater severity than its comparison area.

Sites have begun to collect and submit specimens for analysis, as shown in Table 10. The imbalance between intervention and comparison areas is apparent in volume of specimens submitted as well. Surveillance sites in intervention areas submitted nearly three times as many specimens for analysis as comparison-area sites. It is interesting that, although Oklahoma sites generated the most total volume in Year 2, North Carolina, with the next largest system measured by numbers of sites, generated fewer specimens than Michigan. In general, however, total specimens submitted seem to be determined by the number of participating sites. Righting the balance in surveillance will require efforts from the demonstration projects to increase the numbers of sites in comparison areas.

Table 10

Medicare Influenza Vaccination Demonstration Cost-Effectiveness Study

Total Number of Specimens Submitted
Year 2

	COMMUNITY		HOSPITAL		TOTAL	
	Intervention	Comparison	Intervention	Comparison	Intervention	Comparison
Arizona	74	3	0	0	74	3
Massachusetts	130	107	68	16	198	123
Michigan	361	201	1	5	362	206
New York	150	*	130	*	280	*
North Carolina	271	199	0	0	271	99
Ohio	97	64	26	0	123	64
Oklahoma	943	111	115	50	1058	161
Pennsylvania	46	15	27	1	73	16
Texas	187	110	7	1	194	111
Total	2259	810	374	73	2633	783

* The New York demonstration could not provide data on specimens in its comparson area.

Source: Estimates made from demonstration site records, through 2/9/90

IV. COST-EFFECTIVENESS

A. The Evaluation Process

The chief benefits resulting from Medicare coverage of influenza vaccine are expected to be: 1) a reduction in Medicare hospital admissions for P and I (and a consequent reduction in Medicare hospital payments), and 2) a decline in mortality related to P and I. The primary cost of the benefit to the Medicare program is, of course, the added outlay for influenza vaccine and for its administration. The overall strategy for the evaluation is to estimate the benefits of vaccine coverage by comparing annual outcomes (Medicare P and I hospital admissions, Medicare outlays, deaths related to P and I) between intervention and comparison areas. The expected cost of vaccine coverage hinges for the most part on the number of Medicare beneficiaries who would seek to be vaccinated if influenza vaccine became a covered benefit. The survey of beneficiaries will be conducted in each year of the demonstration in order to estimate the effect of vaccine coverage on vaccination rates.

The specific components of the analysis to be conducted in the demonstration evaluation are contained in the evaluation design plan, submitted as part of the evaluation component of the project. This plan will be reviewed by the TAG in the early Spring 1990. Therefore, a complete description of data elements for the cost-effectiveness equations will not be delineated here. We do, however, present the overall outline of the evaluation.

B. Influenza Vaccine as a Covered Benefit

Medicare coverage of influenza vaccine is hypothesized to result in a net saving to the Medicare program as a whole. That is, it is conjectured that the added cost of vaccine coverage to the program will be more than offset by the reduction in Medicare outlays for P and I hospital stays.

The estimated cost of a Medicare vaccine benefit requires particular attention because the cost per beneficiary during the demonstration is likely to differ from the cost per beneficiary under a well-established benefit. It will be necessary to assume that within a few years after the establishment of a Medicare influenza vaccine benefit, all Medicare enrollees who seek vaccination will do so at Medicare's expense. There seems no reason to believe that any but a small fraction of enrollees would continue to pay for vaccination out-of-pocket if Medicare coverage becomes available. Nor is it likely that current programs providing vaccination to the elderly through State and local health departments would continue at their present levels after institution of a Medicare benefit. This point is crucial because Medicare now receives the benefit of hospitalizations averted as a result of vaccinations paid for privately or by State and local governments. Under a vaccine benefit, the Medicare program would bear the cost of these vaccinations that would have occurred in the absence of a benefit, but will not receive any additional savings in decreased utilization as a result of them. A finding that cost savings associated with the reduction in P and I hospitalizations exceed the cost of incremental vaccinations will not be sufficient to demonstrate the cost-effectiveness of Medicare vaccine coverage. Rather the cost savings must exceed the cost of all vaccinations likely to be sought by Medicare beneficiaries.

It can be shown that the total cost saving to Medicare associated with institution of a vaccine benefit is equal to the difference in P and I hospitalization rates for vaccinated and nonvaccinated beneficiaries, multiplied by the average Medicare hospital payment per P and I stay, multiplied by the change in vaccination rates brought about by Medicare coverage. To arrive at a measure of the net cost saving, the cost to Medicare of all vaccines administered under the benefit must be subtracted from this total.

C. Evaluation Design

In order to predict the cost-effectiveness of a Medicare vaccine benefit, it is necessary to estimate the decline in Medicare admissions (and associated Medicare hospital outlays) and the decline in P and I-related deaths attributable to Medicare coverage during the demonstration. These estimates will form the basis for a computation of the net benefit of vaccine coverage. Subsidiary questions involve the estimation of the efficacy of the vaccine itself in reducing rates of mortality and hospitalization and estimation of the responsiveness of vaccination rates to Medicare coverage.

The research methodology entails a comparison of levels and changes in percapita Medicare P and I admissions, P and I-related deaths, rates of vaccination, and Part A outlays between each set of paired intervention and comparison areas and between the combined set of beneficiaries living in all intervention and comparison areas. Four-way comparisons, that is comparisons of the change in an outcome measure from predemonstration to demonstration periods for intervention and comparison areas, offer the best protection against bias. If percapita Medicare P and I admissions at a particular site are represented by the variable A, with subscripts 0 and 1 representing baseline and demonstration period

values, and with superscripts I and C representing intervention and comparison areas, then the four-way estimator of the effect of vaccine coverage during the demonstration is given by:

$$\text{Coverage Effect} = (A^I_1 - A^I_0) - (A^C_1 - A^C_0).$$

If vaccine coverage truly lowers hospital admission rates, then the estimated effect is expected to be negative. The statistical significance of the estimator can be evaluated by means of a simple test. Similar estimators for the effects of coverage on vaccination rates, mortality rates, and Medicare outlays per capita will be computed. Data for the analysis will be drawn from the beneficiary vaccination surveys to be conducted in each year of the demonstration. Because very little vaccine was administered under the demonstration grants during the 1988-89 flu season, we plan to use this period as a baseline for measuring pre-intervention levels of outcome measures and vaccination rates. (Absence of suitable data on vaccination rates prevents the use of any earlier period as a baseline.)

The major difficulty confronting the evaluation is the natural year-to-year variability in the type and severity of influenza itself. As noted earlier, the measured benefit of vaccine coverage is sensitive to the extent of flu and to the efficacy of the vaccine in preventing hospitalization during the years in which the demonstration is being conducted. A sequence of particularly harsh flu epidemics (or of years with very mild flu) or of bad matches between the vaccine formula and the dominant flu strain could result in a skewed measure of the true long term cost-effectiveness of vaccine coverage. Because there is no convenient method of

separating seasonal factors from the "average" intensity of influenza over time, the judgment of the TAG will be of particular value in assessing the applicability of results obtained during demonstration years.

D. Data for the Cost-Effectiveness Analysis

The evaluation contractor will work with HCFA staff to estimate cost-effectiveness using the following data.

- **Data from the demonstration sites:** These include flu surveillance, vaccine utilization monitoring data, administrative records, vital statistics on pneumonia, and influenza deaths.

- **Data from influenza vaccination surveys:** Data collection is to include annual telephone surveys of randomly-selected Part B-eligible beneficiaries in each site and mail surveys of nursing homes and residential care facilities. These surveys will be used to determine vaccination rates in intervention and comparison areas each year of the study among beneficiaries identified at high and low risk for hospitalization or death due to influenza. The first surveys were conducted in the spring of 1989.

- **Data from the Federal Government:** These include claims records of Medicare Parts A and B utilization, from the Medicare Automated Data Retrieval System (MADRS); information on beneficiary characteristics and status, from Medicare's Health Insurance Master File; area-level data on numbers and charges for Part B reimbursed procedures, from the Part B Medicare Annual Data (BMAD.I) file; beneficiary-level Part B utilization for a 5 percent sample of beneficiaries, from the BMAD.IV file; area-level demographic and socioeconomic data, from the Area Resource File; data from influenza vaccine claims submitted under the demonstration.

- **Data from other sources:** Review of past and ongoing research into influenza and its control will provide information that can be used to validate findings from the demonstration or that, in some cases, will furnish data not collected under the demonstration, such as payor shares of vaccine costs and medical care utilization (Medicare, other third parties, out-of-pocket).

E. Current Status of the Cost-Effectiveness Evaluation

The cost-effectiveness evaluation requires valid baseline and follow-up estimates of influenza vaccination rates in order to determine whether vaccination rates have increased in intervention areas while remaining relatively stable in comparison areas. There are no pre-existing data for the Medicare population that permit estimation of vaccination rates on a county level. Therefore, is necessary to conduct a survey, that will be repeated annually during the demonstration, in order to determine vaccination rates that will enable assessment of the effect of Medicare coverage.

In the first year of the demonstration, noninstitutionalized Medicare beneficiaries in the nine demonstration areas were surveyed by telephone. A second round of telephone interviews was conducted in the four States in the autumn of 1989. A mail survey of nursing homes was conducted to estimate vaccination rates for institutionalized beneficiaries in the study areas.

The Beneficiary Vaccination Survey

The survey was administered to a sample of Medicare Part B beneficiaries for each of the nine intervention sites and a sample with similar demographic composition from each comparison site. A proportionate stratified sample of beneficiaries was drawn for each intervention site from the Health Insurance Type A Master Identification File. The available stratifiers were demographic variables; i.e., age, gender, and race.

Sample sizes for the first survey were selected using the conservative assumption that vaccination rates among the elderly average roughly 20 percent (see Section 1.2). Wishing to have the ability to detect even a small effect on the vaccination rate, perhaps no more than five percentage points, required a sample size of 940 completed interviews from each intervention and each

comparison site, for a minimum of 16,920 interviews. Higher baseline vaccination rates would require larger beneficiary samples to detect a five percentage point effect.

After selecting large probability samples for each of the nine pairs of sites, telephone numbers were obtained through a computer matching service. Phone numbers were available for approximately 65 percent of the initial sample. While this is higher than the 50 percent match rate that is typically achieved for the general population, it is not clear whether and how the unmatched beneficiaries differ from those for whom phone numbers were obtained. Included in this unmatched group are persons in institutions, those without telephones or with unlisted numbers, and those living with a person whose name and address did not appear on the HCFA data file. The response rate to the survey was 60 percent; 17,643 surveys were completed.

Vaccination rates for intervention and comparison areas in each demonstration site are shown in Table 11. The overall vaccination rate for all respondents was 43 percent. Site and area specific rates ranged from 37 percent (Massachusetts Comparison) to 56 percent (New York Intervention). The New York demonstration showed the largest difference between intervention and comparison areas (5.95 percentage points), and the Michigan demonstration showed the smallest difference (0.33 percentage points).

Table 12 reports the vaccination rate by age category and by presence or absence of certain risk factors defined by CDC. On average, older beneficiaries and those who reported the presence of risk factors were more likely to be vaccinated than others.

Table 11

Medicare Influenza Vaccination Cost-Effectiveness Study

Vaccination Rate by Site & Area

SITE	INTERVENTION	COMPARISON
Arizona	47.5 %	47.9 %
Massachusetts	39.0	37.0
Michigan	41.1	41.2
New York	55.6	49.7
North Carolina	40.9	37.2
Ohio	42.1	39.5
Oklahoma	42.6	40.2
Pennsylvania	45.1	41.9
Texas	46.3	41.8

Source: First Annual Medicare Beneficiary Influenza Vaccination Survey (April-July, 1989)

Table 12

Medicare Influenza Vaccination Cost-Effectiveness Study

VACCINATION RATES BY AGE & HEALTH RISK STATUS*

AGE	HEALTH RISK PRESENT	HEALTH RISK ABSENT	TOTAL RESPONDENTS
<65	35.9%	21.9%	1,259
65-75	47.5%	37.0%	10,310
>75	51.7%	44.5%	6,074
TOTAL	48.1%	38.6%	17,643

* Health Risk is defined as presence of any of the following: heart disease, lung disease, renal disease, diabetes, or immunosuppression due to any cause.

Source: First Annual Medicare Beneficiary Influenza Vaccination Survey (April-July, 1989)

The settings where respondents obtained their influenza vaccine were also examined. The majority reported receiving it at a private physician's office. Another 19 percent reported receiving vaccine at government clinics; 5 percent were vaccinated in the hospital outpatient setting, 4 percent at a community or senior center, and 4 percent at an HMO. The remaining 8 percent were vaccinated in their workplace, at the hospital during an inpatient stay, by a visiting nurse, or in another setting. The survey also asked whether respondents had received a pneumococcal vaccination. Results indicated that 24 percent of respondents had received one.

The reported vaccination rates from this survey are higher than those in other surveys, which range from 19 to 36 percent. (See Section 1.2.) The major difference between this and previous surveys was in the method used to find elderly persons to interview. Other surveys commonly used a random digit dialing approach to sample households (with telephones) and then asked for anyone over age 65 to respond to questions about influenza vaccination. This survey identified Part B beneficiaries, then obtained their telephone numbers and conducted interviews. This approach was necessary so that HCFA claims data could be linked to individuals' survey responses. Validation studies will be conducted to determine if this survey procedure introduced any bias.

In order to produce (and then detect) differences between intervention and comparison areas in outcomes such as hospitalizations, significant increases in vaccination rates will be necessary. This is particularly true for rarer outcomes, such as decreased mortality in intervention areas. If the high vaccination rates reported in this survey are correct, the demonstration task of increasing vaccination rates could become more difficult than expected.

A second beneficiary survey was conducted, with interviews beginning in April, and continuing through the middle of June 1990.

The Nursing Home Survey

The Medicare/Medicaid Provider of Service file was selected as the sampling frame for the nursing home survey. All 1,085 of the nursing homes in the demonstration intervention or comparison areas were selected from this list. Cover letters and surveys were mailed to all facilities. After deleting facilities for reasons such as not having any residents, not having any Medicare residents, being out of business or duplication, there remained a total net sample of 845. We received completed surveys from 430 of these, resulting in a response rate of total completed surveys relative to total net sample of 51 percent.

Any record containing missing values that implied vaccination rates greater than 100 percent was deleted from the file. This final editing step left 389 usable records for analysis. Dividing this number by the 1,085 surveys initially delivered results in an overall usable response rate of 38.9 percent.

Table 13 illustrates the distribution of nursing home facilities having a written policy encouraging the administration of influenza vaccine for residents. The Michigan demonstration had the highest overall percentage (84) of such facilities and Oklahoma has the lowest percentage (48). The remaining sites had comparable percentages all within the range of 57-81 percent. In four cases, a greater proportion of facilities in the intervention areas, relative to their comparison areas, had such a policy.

The actual number of residents vaccinated, as well as the calculated influenza vaccination rates for responding nursing homes, are shown in Table 14. North Carolina facilities had the highest overall rate. Of the 6,360 Medicare eligible residents in

Table 13

Medicare Influenza Vaccination Cost-Effectiveness

NURSING HOMES WITH IMMUNIZATION POLICIES

SITE	# NH RESPONDING	# NH WITH POLICY	% NH WITH POLICY
Arizona			
Intervention	22	12	54.5%
Comparison	6	4	66.7%
Total	28	16	57.1%
Massachusetts			
Intervention	15	13	86.7%
Comparison	22	17	77.3%
Total	37	30	81.1%
Michigan			
Intervention	23	18	78.3%
Comparison	26	23	88.5%
Total	49	41	83.7%
New York			
Intervention	19	14	73.7%
Comparison	8	5	62.5%
Total	27	19	70.4%
North Carolina			
Intervention	33	28	84.8%
Comparison	26	20	76.9%
Total	59	48	81.4%
Ohio			
Intervention	25	18	72.0%
Comparison	26	22	84.8%
Total	51	40	78.4%
Oklahoma			
Intervention	27	12	44.4%
Comparison	60	30	50.0%
Total	87	42	48.3%
Pennsylvania			
Intervention	29	25	86.2%
Comparison	24	15	62.5%
Total	53	40	75.5%
Texas			
Intervention	13	11	84.6%
Comparison	26	16	61.5%
Total	39	27	69.2%

Source: First Annual Nursing Home Influenza Vaccination Survey (April-July, 1989)

Table 14
Medicare Influenza Vaccination Cost-Effectiveness Study

PERCENTAGE OF PATIENTS VACCINATED

SITE	#NH RESPONDING	# PATIENTS*	# PATIENTS VACCINATED	% PATIENTS VACCINATED
Arizona				
Intervention	21	3619	1894	52.3%
Comparison	6	720	512	71.1
Total	27	4339	2406	55.5
Massachusetts				
Intervention	15	1544	1037	67.2
Comparison	19	1672	1320	78.9
Total	34	3216	2357	73.3
Michigan				
Intervention	23	2610	1765	67.6
Comparison	22	3723	2829	76.0
Total	45	6333	4594	72.5
New York				
Intervention	17	2685	2103	78.3
Comparison	8	1383	1254	90.7
Total	25	4068	3357	82.5
North Carolina				
Intervention	32	3875	3183	82.1
Comparison	23	2485	2112	85.0
Total	55	6360	5295	83.3
Ohio				
Intervention	24	2803	2364	84.3
Comparison	24	2799	2270	81.1
Total	48	5602	4634	82.7
Oklahoma				
Intervention	24	1508	941	62.4
Comparison	54	4679	3426	73.2
Total	78	6187	4367	70.6
Pennsylvania				
Intervention	20	2848	1965	69.0
Comparison	22	2188	1388	63.4
Total	42	5036	3353	66.6
Texas				
Intervention	12	1267	809	63.9
Comparison	23	2652	1812	68.3
Total	35	3919	2621	66.8

* Figures reflect the number of residents aged 65 and over in the responding nursing homes

Source: First Annual Nursing Home Influenza Vaccination Survey (April-July, 1989)

the reporting facilities, 5,295 (83 percent) had been vaccinated. The facilities in Arizona had the lowest aggregate rate. The reporting facilities noted that 2,406 (56 percent) of their 4,339 Medicare-eligible residents had been vaccinated. Rates in other areas were in the range of 66-82 percent. The Arizona site also shows the greatest difference between its intervention and comparison area with respect to vaccination rate (18.8 percentage points). It is interesting that, except in the Ohio and Pennsylvania sites, the comparison areas had higher rates of vaccination than did the intervention areas.

The above results are based on small numbers of responses and are insufficient to permit generalization to all nursing homes in the demonstration areas. They will be utilized cautiously in estimating baseline vaccination rates in the institutionalized beneficiary population. A more extensive effort, including custodial care and residential facilities not certified by Medicare, may increase the number of responses enough to support estimates of vaccination rates among institutionalized beneficiaries. Alternative methods of increasing responses to the nursing home survey will be discussed with the TAG. The second nursing home survey was initiated in April 1990.

Other Data Needed for the Evaluation

Apart from the analysis of results from the first year's vaccination survey, the cost-effectiveness evaluation itself is not yet underway. The primary data for hospital utilization and outlays are to be retrieved from the MADRS. Since the process of submitting claims, processing by a Medicare fiscal intermediary and entry of data to MADRS may sometimes require 10 to 12 months, analysis of first-year data could not begin before mid-summer of 1990.

Moreover, since little vaccine was administered during the first year of the demonstration, it is unlikely that useful results will be forthcoming until data from the second year of the demonstration (influenza season 1989-90) are available. These data will not be complete until the summer of 1991.

We believe that a 4-year demonstration will be necessary to provide sufficient duration for an accurate assessment of the costs and benefits of Medicare vaccine coverage. This is particularly true because of the late start and consequent paucity of data from the first year of the demonstration. This, together with the unavoidable lags in Medicare claims submission and processing, makes it impossible to assemble complete data on utilization and payments to complete a cost-effectiveness study within the 2 year time frame. Furthermore, the natural year-to-year variability in rates of illness and hospitalization due to flu argues strongly for a 4-year rather than a 2-year demonstration.

V. CONCLUSIONS

OBRA 1987 required a preliminary Report to Congress on the first 2 years of the Medicare influenza vaccination demonstration to justify either adding a vaccine benefit on November 1, 1990 or suspending judgment until 2 additional years of data under the demonstration are analyzed. This report has addressed this question.

A. Justification for Continuing the Demonstration

It is recommended that this demonstration continue for an additional 2 years because data generated in the first 2 years are insufficient to support a valid estimate on the cost-effectiveness of a Medicare influenza vaccine benefit. The following points summarize the evidence in support of this recommendation.

- **Preparations for the demonstration during 1988 conflicted with vaccine distribution objectives.** The first 10 months of 1988 were required to plan and design the demonstration, negotiate with manufacturers for the purchase of vaccine, announce, review and award demonstration grants and assist successful applicants in preparing their operational protocols. As a result, vaccine was not shipped to the sites until the end of the optimum vaccination period, which is September through November. During the first year, 26,000 doses were administered, well below initial expectations. Therefore, only in the second year has demonstration activity begun to approach levels needed to produce usable evaluation data and to meet congressional targets for spending on this project.

- **Greater availability of vaccine will be needed to test the capacity of a Medicare benefit to increase vaccination rates.** Initial survey estimates showed baseline vaccination rates to be higher than expected, averaging over 40 percent. The Medicare

vaccine benefit would be more likely to encourage a net increase in influenza vaccinations if relatively few beneficiaries were vaccinated before the benefit. More "first time" vaccinations would occur under the demonstration. Fewer beneficiaries would substitute Medicare as payer, having used other payers in previous years. If a net increase in vaccinations cannot be detected, it will be difficult to use data from the demonstration to argue that an influenza vaccine benefit is cost-effective. Therefore, to detect an effect, the amount of vaccine provided through the demonstration will have to be larger than would have been needed had the rate proved to be the expected 20 percent.

- **Some demonstration projects experienced significant delays in implementing data collection and monitoring systems.** Sites with complex subcontracting arrangements spent much of the first year resolving organizational issues. Sites with limited previous experience needed time to develop protocols and hire appropriate staff. These delays meant that site-level baseline information, from the first year of the demonstration, was not available for some of the projects.

- **Recent research initiatives require time to yield data for the study.** Statewide projects, implemented during the second year of the demonstration, will provide data on the effect of Medicare coverage on vaccination rates, independent of the effects of intensive outreach programs. These data will be needed to assess the cost-effectiveness of adding a Medicare vaccine benefit. Unless the demonstration is extended, statewide data from only one flu season (1989-90) will be available for analysis.

The tenth demonstration site (Illinois), added to increase vaccine distribution and expand the data available for the assessment of cost-effectiveness, will be operational during the first flu season covered by its grant (1990-91). Complete data from the Michigan vaccine efficacy study will also not be available

until late 1990. Therefore, results from these two important components will be unavailable unless the demonstration is extended.

- The nature, extent and severity of influenza vary from season to season. Thus, estimates of the cost-effectiveness of an influenza vaccine benefit based on data from only one season will be suspect. Data from two additional seasons will strengthen the findings by showing the sensitivity of cost-effectiveness estimates to the characteristics of different flu epidemics.

B. Plans for the Extended Demonstration

During the extended demonstration, the following data collection and evaluation tasks will be completed.

HCFA and CDC will continue efforts to meet the congressionally-mandated level of $25 million in annual expenditure for this demonstration. Funding of the 10 demonstration sites will be continued. Within overall expenditure limits, HCFA will explore the feasibility of expanding coverage through the demonstration to additional statewide sites. New methods of publicizing the demonstration to beneficiaries will be explored.

In each of the nine original demonstration projects, two additional beneficiary and nursing home surveys will be conducted. This means that vaccination data from one baseline and three post-implementation periods will be available, capturing effects due to changes in the severity of flu epidemics over four seasons. In the tenth site and the four statewide sites, one baseline and two post-implementation surveys will be conducted.

The University of Michigan will complete a vaccine efficacy study utilizing data collected during the 1989-90 flu season. This grant will continue to be monitored by a special subcommittee of the Medicare Influenza TAG.

Abt Associates, Inc., will continue to provide technical assistance to existing projects and to Illinois and will evaluate the demonstration and estimate the cost-effectiveness of a Medicare vaccine benefit. A summary report on the results of the cost-effectiveness analysis will be submitted in August 1992, utilizing data available at that time. This report will analyze the effects of the demonstration on vaccination rates and the effects of vaccination on health care outcomes. Estimates of the cost-effectiveness of a Medicare influenza vaccine benefit, under alternative assumptions about the structure of the benefit, will be computed. It will serve as the basis for the Secretary's recommendation to Congress. A final report of the evaluation will be submitted in September 1993. This report will update the cost-effectiveness analysis using the most recent data from the last year of the demonstration and will assess characteristics of the individual demonstration projects that affected findings of the study.